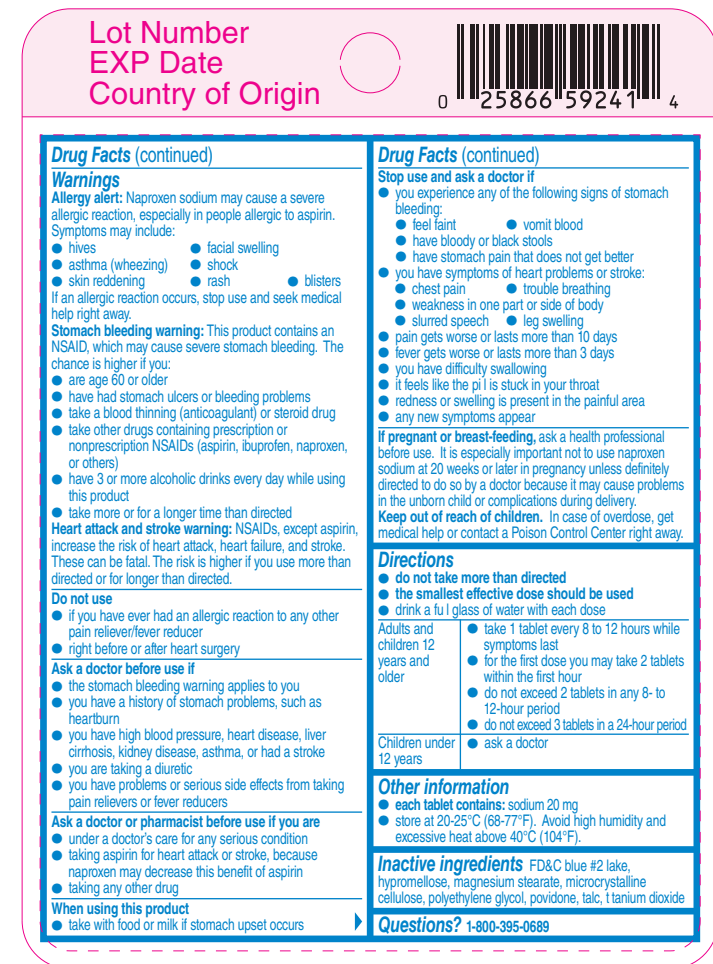




FRONT



BACK

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings*	8 pt-bold italic*	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0.5 pt	0 - 0.5 pt
Hair lines	0.5 pt rule	0.5 pt
Box and Barlines†	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2.5pt rule

ALL DAY STRONG®

ALEVE®

naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

**STRENGTH TO
LAST 12 HOURS**

**10
TABLETS**

Read Vial Blister Card Before Use.
Uses: temporarily relieves minor aches and pains and temporarily reduces fever. **Warnings:** Allergy alert: Naproxen sodium may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing) or shock. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed.

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor or pharmacist before use if you are taking any other drug. Stop use and ask a doctor if you experience any of the following signs of stomach bleeding** (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), or if pain or fever gets worse. **If pregnant or breast-feeding,** ask a health professional before use. **Directions:** **Do not take more than directed. The smallest effective dose should be used.** Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 tablet every 8 to 12 hours while symptoms last. For the first dose you may take 2 tablets within the first hour. Do not exceed 2 tablets in any 8- to 12- hour period. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)**
 Dist. by:
 Bayer HealthCare LLC
 Whippany, NJ 07981 00000

Lot/Exp Date Area

200%

ALL DAY STRONG®

ALEVE®

naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

**STRENGTH TO
LAST 12 HOURS**

**10
TABLETS**

Read Vial Blister Card Before Use.
Uses: temporarily relieves minor aches and pains and temporarily reduces fever. **Warnings:** Allergy alert: Naproxen sodium may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing) or shock. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed.

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor or pharmacist before use if you are taking any other drug. Stop use and ask a doctor if you experience any of the following signs of stomach bleeding** (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), or if pain or fever gets worse. **If pregnant or breast-feeding,** ask a health professional before use. **Directions:** **Do not take more than directed. The smallest effective dose should be used.** Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 tablet every 8 to 12 hours while symptoms last. For the first dose you may take 2 tablets within the first hour. Do not exceed 2 tablets in any 8- to 12- hour period. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)**
 Dist. by:
 Bayer HealthCare LLC
 Whippany, NJ 07981 00000

Lot/Exp Date Area

Actual Size 100%

FDA00295-1

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [§]	-
Drug Facts Continued	7 pt [§]	-
Headings	7 pt-bold italic [§]	4.5 pt
Subheadings	6 pt [§]	4.5 pt
Body Text	6 pt [§]	4.5 pt
Bullets	5 pt	6 pt
Headlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

[§]Characters per inch rule is not applicable to ICL.
[§]ICL minimum font size is 4.5 pt.
[†]< 0.5 pt. leading may be used as long as ascenders and descenders do not touch.
[†]FDA recommends size 2.5 pt type



88368142

Do not use if carton is open or if seal is missing or broken.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Do not use if you have a history of stomach problems, such as heartburn.

Do not use if you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke.

Do not use if you are taking a diuretic.

Do not use if you have problems or serious side effects from taking pain relievers or fever reducers.

Do not use if you experience any of the following signs of stomach bleeding:

- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Do not use if you are pregnant or breastfeeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period
- ask a doctor

Children under 12 years

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

ALL DAY STRONG®
ALEVE®
naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

STRENGTH TO LAST 12 HOURS

ACTUAL SIZE
24 TABLETS

Drug Facts (continued)
Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

LOT EXP MADE IN Bayer

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Do not use if you have a history of stomach problems, such as heartburn.

Do not use if you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke.

Do not use if you are taking a diuretic.

Do not use if you have problems or serious side effects from taking pain relievers or fever reducers.

Do not use if you experience any of the following signs of stomach bleeding:

- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk, if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
 - you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
 - pain gets worse or lasts more than 10 days
 - fever gets worse or lasts more than 3 days
 - you have difficulty swallowing
 - it feels like the pill is stuck in your throat
 - redness or swelling is present in the painful area
 - any new symptoms appear

Active ingredient (in each tablet)
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*.....Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Purposes

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - menstrual cramps
 - toothache
 - minor pain of arthritis
 - headache
 - the common cold
- temporarily reduces fever

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - menstrual cramps
 - toothache
 - minor pain of arthritis
 - headache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

DRUG FACTS INFO (Updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings [†]	8 pt-bold italic [†]	8 pt
Subheadings	>6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	>0.5 pt	0 pt - 0.5 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines [†]	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP
[†] FDA Recommends 2.5pt rule

88368096



Do not use if carton is open or if foil seal imprinted with Bayer HealthCare on bottle opening is missing or broken.

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- if feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981
Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.

Bayer

Drug Facts

Active ingredient (in each tablet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*.....Pain reliever/fever reducer

Purposes
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - headache
 - the common cold
- temporarily reduces fever
- menstrual cramps
- toothache

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

9608



QUIET ZONE QUIET ZONE

LOT EXP MADE IN

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt.-bold italic†	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 pt. - 0.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Berline†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 38	≤39

** Headings are to be at least 20% larger than Body Text.
† Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2.5pt. rule

88368134



Do not use if carton is open or foil seal imprinted with Bayer HealthCare® on bottle opening is missing or broken.

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.
Dist. by: Bayer HealthCare LLC
Whippany, NJ 07981

Drug Facts

Active ingredient (in each tablet)
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*..... Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Purposes

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - headache
 - menstrual cramps
 - toothache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin redness
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

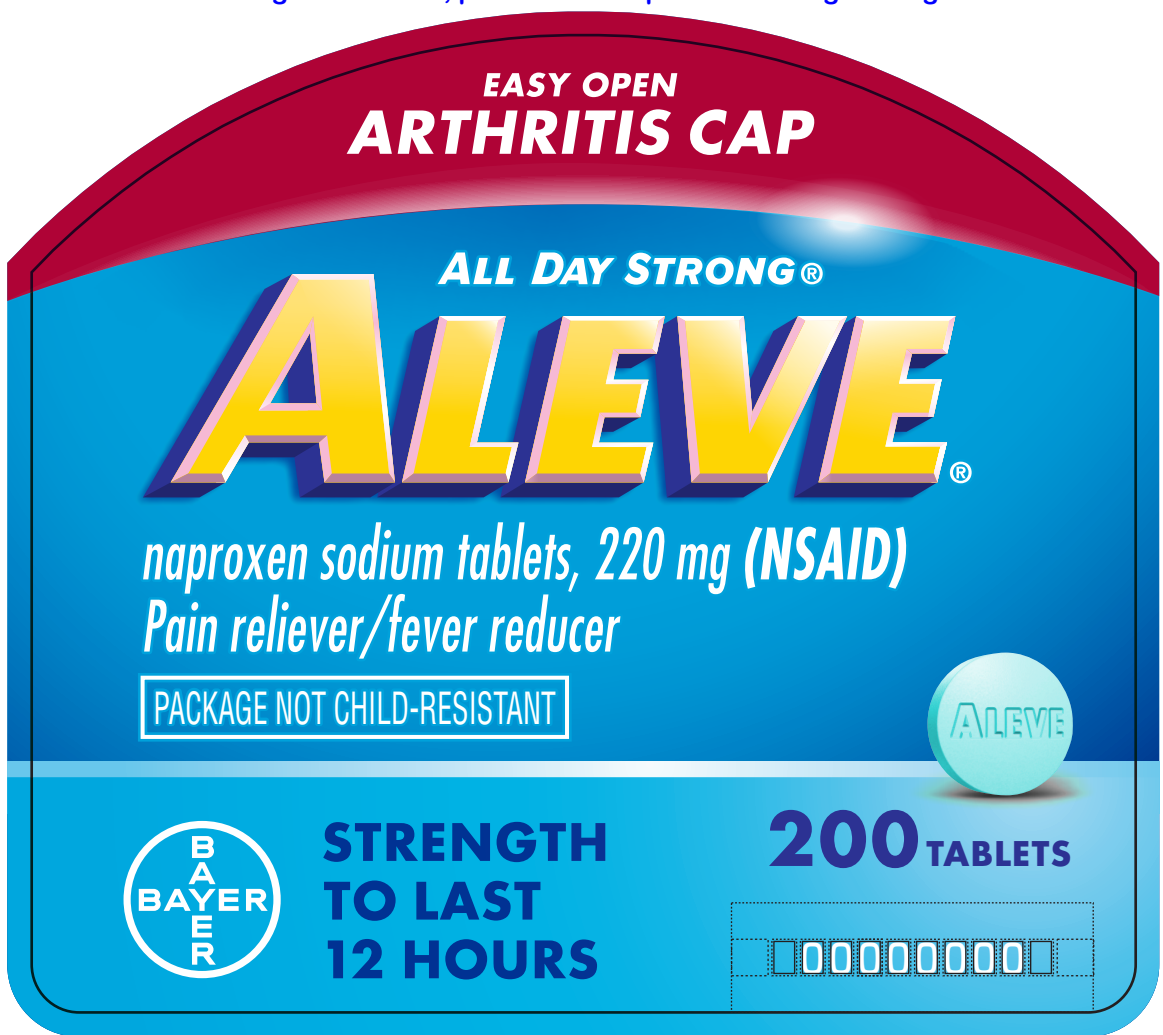
- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

LOT EXP MADE IN



DRUG FACTS INFO (updated 5/18/15)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 pt. - 0.5 pt.
Hair lines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	<39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP
^{††} FDA Recommends 2.5pt rule

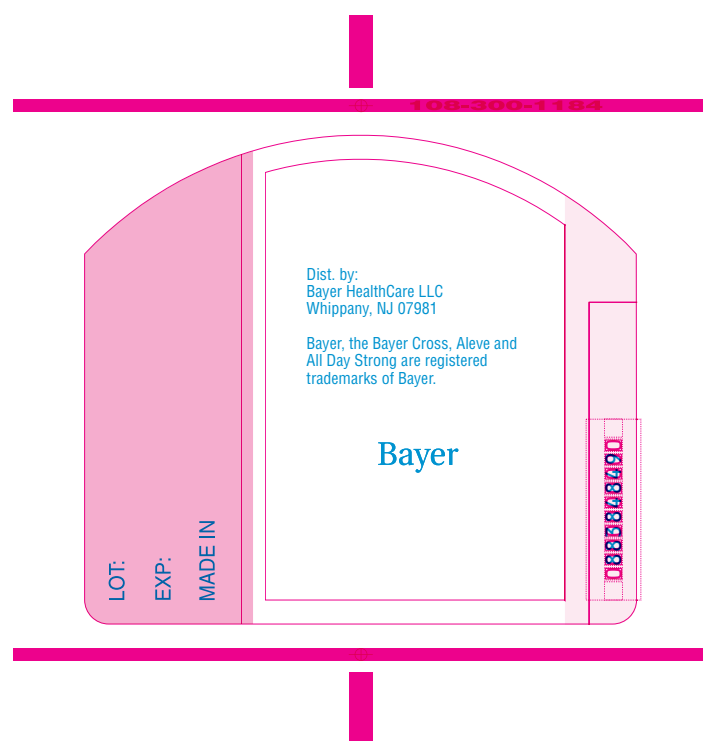


200%



Actual Size 100%

FDA00274-5



Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

OPEN TO READ DRUG FACTS BEFORE USE

0 25866 59235 3

Drug Facts

Active Ingredient (in each tablet)
Naproxen sodium (Naproxen, 200 mg) (NSAID)
Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Drug Facts (continued)

Warnings

- temporarily relieves minor aches and pains due to:
 - minor pain or arthritis
 - muscle aches
 - backache
 - headache
 - the common cold
 - temporarily reduces fever

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years: ask a doctor

Other Information

- each tablet contains sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Contains Ingredients: FD-C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyurethane, titanium dioxide

Questions or comments? 1-800-368-4000 (M-F 9AM-5PM EST)

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain or arthritis
 - muscle aches
 - backache
 - headache
 - the common cold
 - temporarily reduces fever

Warnings

- **Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
 - hives
 - facial swelling
 - asthma (wheezing)
 - skin redness
 - skin rash
 - shock
 - rash
- If a serious allergic reaction occurs, stop use and seek medical help right away.
- **Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
 - are age 60 or older
 - have had stomach ulcers or bleeding problems
 - have taken aspirin, ibuprofen, or other NSAIDs
 - have other drugs, containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
 - have 3 or more alcoholic drinks every day while using this product
 - have more or for a longer time than directed
- **Heart attack and stroke warning:** NSAIDs, except aspirin, may increase the risk of heart attack or stroke. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if:

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn, indigestion, or ulcers
- you are taking a diuretic
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are:

- under a doctor's care for any serious condition
- being aspirin for heart attack or stroke, because naproxen may increase the benefit of aspirin
- using any other drug
- taking any other drug
- taking any other drug
- taking any other drug

Stop use and ask a doctor if:

- you experience any of the following signs of stomach upset occurs
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- you have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - dizziness or lightheadedness
 - pain gets worse or lasts more than 30 days
 - fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt. bold italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines [‡]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

[†] Headings are to be at least 6 pts larger than Body Text.
[‡] Drug Facts Title to be larger than all other type size used in DCP
[‡] FDA Recommends 2.5pt. rule

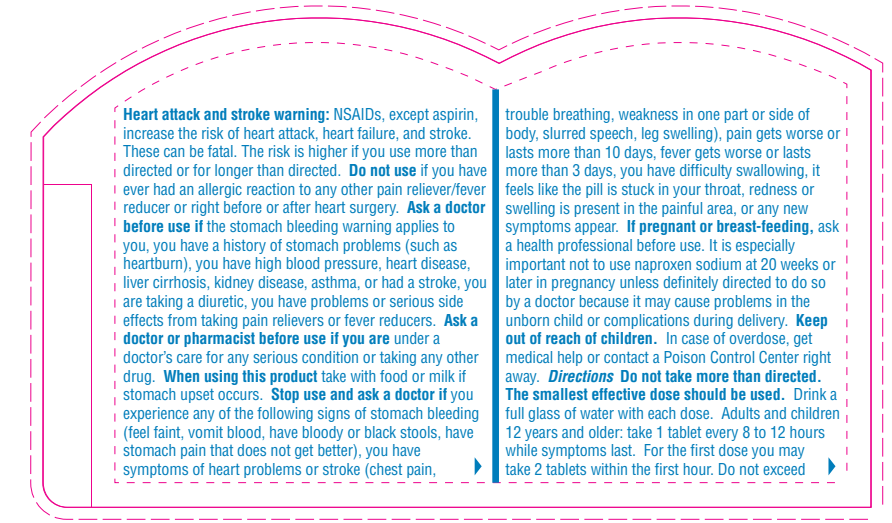
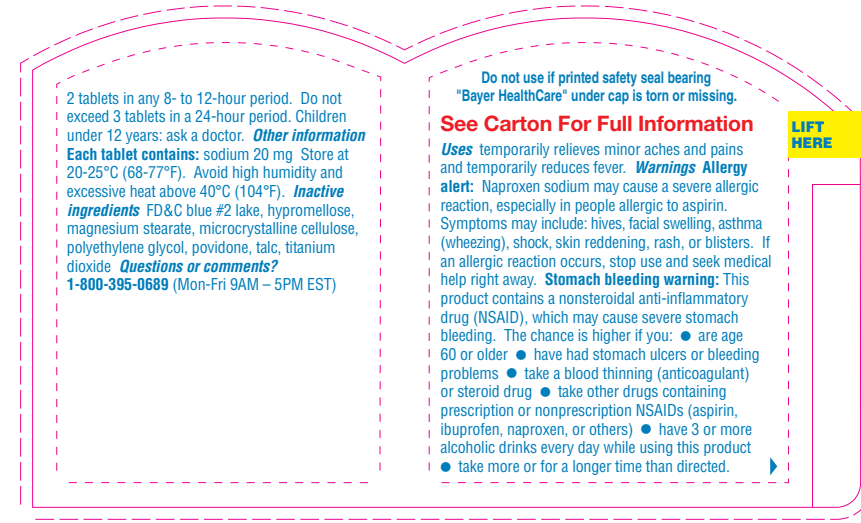
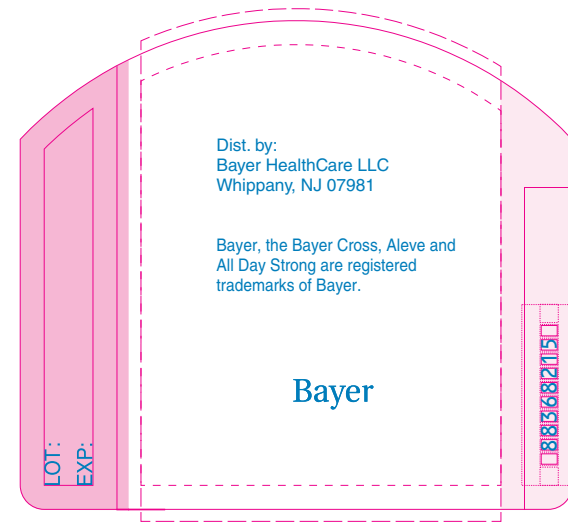


200%



Actual Size 100%

FDA00386-2



DRUG FACTS INFO: (Modified Format - updated 3/1/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt-bold italic*	6 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	6 pt	12 pt
Leading	≥0 pt	1 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† Box Bar line may be omitted and color contrast used to highlight Drug Facts Info



CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>=8 pt.**	8 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold, 10 pt. ^{††}	8 pt.
Subheadings	>=6 pt.	6 pt.
Body Text	>=6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	>=0.5 pt.	0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlineart	>=0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 30	<30

^{††} Headings are to be at least 20pt larger than Body Text.
^{†††} Drug Facts Title to be larger than all other type size used in DPP
^{††††} FDA recommends 2.5pt rule

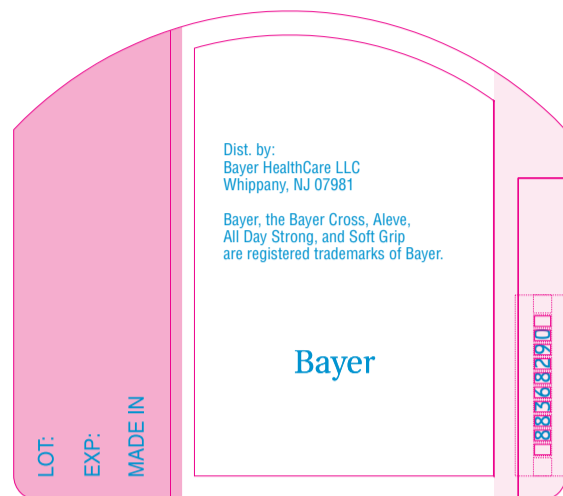


200%



Actual Size 100%

FDA00300-1



Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

OPEN TO READ DRUG FACTS BEFORE USE

0 25866 59345 9

Drug Facts

Active Ingredient (in each tablet)
Naproxen sodium (NSAID)..... Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Drug Facts (continued)

If pregnant or breastfeeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless explicitly directed to do so by a health professional. Use of NSAIDs during pregnancy can cause complications during delivery. Problems in the unborn child or other health problems may occur. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 4 tablets within the first hour
- take 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years: ask a doctor

Other important information

- each tablet contains sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive Ingredients: FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, lact, titanium dioxide

Questions or Comments? 1-800-368-0888 (Mon-Fri 9AM-5PM EST)

Drug Facts (continued)

Usage

- temporarily relieve minor aches and pains due to:
 - muscular aches
 - backache
 - menstrual cramps
 - headache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- stuck or hoarse voice
- difficulty breathing

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product, or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if:

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are:

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease its benefit or aspirin
- taking any other drug

When using this product:

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if:

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - fainting or dizziness
- your pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- redness or swelling is present in the painful area
- any new symptoms appear

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt.-bold italic‡	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Hair-ines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

† Headings are to be at least 20% larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DPP
‡ FDA Recommends 2.5pt. rule



Drug Facts (continued)

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint ● vomit blood ● have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain ● trouble breathing ● weakness in one part or side of body
 - slurred speech ● leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{1,4}	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ⁵	8 pt.-bold/italic ³	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	6.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines ⁶	≥0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 30	< 30

¹ Headings are to be at least 20pt. larger than Body Text.
² Drug Facts Title to be larger than all other type size used in DPP.
³ FDA recommends 2.5pt. rule.

88368150



Do not use if carton is open or if seal is missing or broken.
Bayer Healthcare, on bottle opening is missing or broken.
Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.
Bayer HealthCare LLC
Whisper, NJ 07981

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 caplet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period
- ask a doctor

Children under 12 years

- ask a doctor

Other information

- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

0518



QUIET ZONE QUIET ZONE

Drug Facts (continued)

Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

LOT EXP MADE IN Bayer

Drug Facts

Active ingredient (in each caplet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*.....Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

Purposes

- temporarily reduces fever

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - menstrual cramps
 - toothache
 - backache
 - headache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

STRENGTH TO LAST 12 HOURS

ACTUAL SIZE

24 CAPLETS

CAPSULE-SHAPED TABLETS

DRUG FACTS INFO (updated 5/18/16)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold italic*	8 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 - 0.5 pt.
Horizontal lines	0.5 pt. rule	0.5 pt.
Box and Bar inset	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 30	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type sizes used in DFP
† FDA Recommends 2.5pt. rule

88368487



Do not use if carton is open or if foil seal imprinted with Bayer HealthCare on bottle opening is missing or broken.

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 caplet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981
Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.

Bayer

Drug Facts

Active ingredient (in each caplet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)[†] . Pain reliever/fever reducer

Purposes *nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - headache
 - the common cold
- temporarily reduces fever
- menstrual cramps
- toothache

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

LOT EXP MADE IN



DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{**}	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ^{**}	8 pt.-bold italic ^{**}	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 pt. - 0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 38	≤39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP
^{††} FDA Recommendations 2.5pt. rule



88368789

Do not use if carton is open or if foil seal is missing or broken.

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 caplet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

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Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981

LOT EXP MADE IN



DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{1*}	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ²	8 pt.-bold italic ³	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	6.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

¹ Headings are to be at least 20% larger than Body Text.
² Drug Facts Title to be larger than all other type size used in DFP.
³ FDA Recommends 2.5pt. rule.

88369971



Do not use if carton is open or if foil seal is missing or broken.

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 caplet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981
Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.

Bayer

Drug Facts

Active ingredient (in each caplet)
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*..... Pain reliever/fever reducer

Purposes
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - headache
 - toothache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

LOT EXP MADE IN



DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.8 pt.
Hairlines	0.5 pt rule	0.5 pt.
Box and Barlines [†]	>0.5 pt rule	2.5 pt.
Characters Per Inch [†]	No more than 38	≥39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP
^{††} FDA recommends 2.5pt rule.

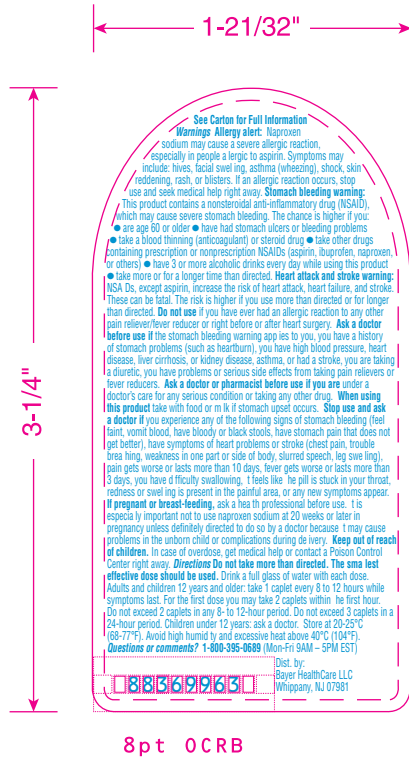


200%



Actual Size 100%

FDA00409-3



DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	-
Drug Facts Continued	8 pt	-
Headings [§]	8 pt-bold italic [§]	4.5 pt
Subheadings	≥6 pt	4.5 pt
Body Text	≥6 pt	4.5 pt
Bullets	5 pt	8 pt
Leading	≥0.5 pt	4.5 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	> 39
[§] Headings are to be at least 2pts larger than Body Text. ^{**} Drug Facts Title to be larger than all other type size used in DFP [†] FDA Recommends 2.5pt rule		



Actual Size 100%

FDA47178-1

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{1*}	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ²	6 pt.-bold italic ³	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines ²	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

¹ Headings are to be at least 2pts larger than Body Text.
² Drug Facts Title to be larger than all other type size used in DPP
³ FDA Recommends 2.5pt rule

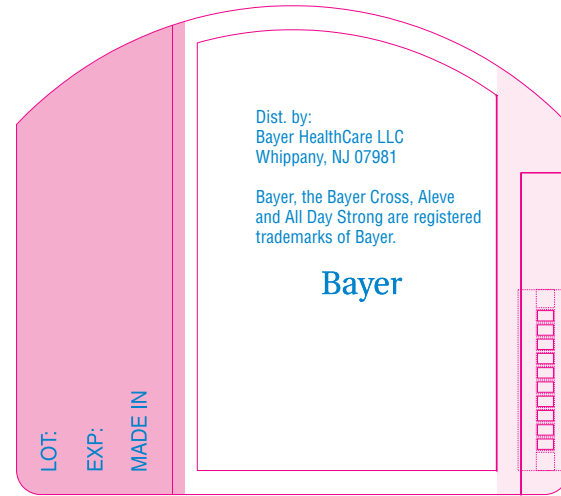


200%



Actual Size 100%

FDA00310-1



Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

OPEN TO READ DRUG FACTS BEFORE USE

LIFT HERE

0 25866 59301 5

Drug Facts

Active Ingredient (in each caplet)
Naproxen sodium (naproxen 200 mg) (NSAID)*

Purposes
Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 caplet every 8 to 12 hours while symptoms last
- if the dose you may take exceeds 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period

Children under 12 years: ask a doctor

Other information

- each caplet contains sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments? 1-800-365-0689 (Mon-Fri 9AM - 5PM EST)

Drug Facts (continued)

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - headache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- swelling of the face, lips, tongue, or throat
- skin rash
- shock
- skin redness
- asthma (wheezing)
- skin itching
- skin redness
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you are 60 or older.

- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you are taking any other pain relievers, such as aspirin
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- pregnant or breast-feeding
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- there are signs of infection (fever, sore throat)
- you have difficulty swallowing
- if it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold italic*	8 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than 1 other type size used in DPP.
† FDA Recommends 2.5pt rule.

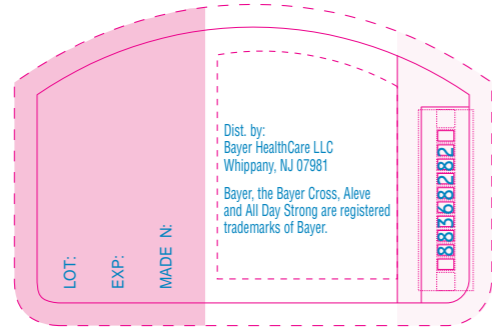


200%



Actual Size 100%

FDA00273-2



Drug Facts (continued)

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - headache
 - toothache
 - the common cold
- temporarily reduces fever

Warnings

Always warn: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- stomach pain
- skin redness
- swollen
- rash
- diarrhea

If an allergic reaction occurs, stop use and seek medical help right away.

Important information: This product contains an NSAID, which may cause serious stomach bleeding. The chance is higher if you:

- are age 65 or older
- take aspirin, blood thinners or blood thinners
- take alcohol
- take other drugs containing NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever or fever reducer
- right before or after heart surgery

Ask a doctor before use if:

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are:

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit
- taking any other drug

When using this product:

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if:

- you experience any of the following signs of stomach bleeding:
 - red, black, or tarry stool
 - stomach pain
 - dark, bloody or black stools
 - dark red or black, tarry stools
 - not get better

Drug Facts (continued)

- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - sudden speech
 - leg swelling
 - swelling in ankles or legs more than 3 days
 - fever, rash, or hives or itchy skin
 - you have difficulty swallowing
 - it feels like the pill is stuck in your throat
 - redness or swelling is present in the painful area
 - any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy, unless definitely directed to do so by a doctor, because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 capsule every 8 to 12 hours with or without food
- for this dose you may take 2 capsules with the first hour
- do not exceed 2 capsules in any 8 to 12-hour period
- do not exceed 3 capsules in a 24-hour period
- ask a doctor

Children under 12 years

- ask a doctor

Other Information

- each white capsule contains 20 mg naproxen sodium (20 mg naproxen) and 250 mg of hydroxypropyl methylcellulose K100
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive Ingredients

FDAC blue P2 dye, hydroxypropylcellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, talc, titanium dioxide

Questions or comments?

1-800-845-6690 (Mon-Fri 9AM - 5PM EST)

Bayer

0 25866159347 3

Drug Facts

Active ingredient (in each capsule): Naproxen sodium 20 mg (naproxen 20 mg) (NSAID)

Other ingredients: Pain reliever/fever reducer, non-steroidal anti-inflammatory drug

Do not use if printed safety seal bearing Bayer HealthCare logo is torn or missing.

DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.5 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt-bold italic*	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	5 pt.
Leading	≥0.5 pt.	6 & 6.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2.5pt rule



DRUG FACTS INFO (Updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold/italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	6.5 pt.
Headlines	0.5 pt rule	0.5 pt.
Box and Barlines [†]	>0.5 pt rule	2.5 pt.
Characters Per Inch	No more than 30	≤ 30

[†] Headings are to be at least 2 pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in ODP.
^{††} FDA Recommends 2.5pt rule.

Drug Facts (continued)

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- you have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 caplet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

Bayer

88384865

SOFT GRIP[®] ARTHRITIS CAP

ALL DAY STRONG[®]

ALEVE[®]

naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

THIS PACKAGE IS CHILD-RESISTANT

BAYER

STRENGTH TO LAST 12 HOURS

270 CAPLETS

CAPSULE-SHAPED TABLETS

5987

Dist. by: Bayer HealthCare LLC
Whippany, NJ 07981

Bayer, the Bayer Cross, Aleve, All Day Strong and Soft Grip are registered trademarks of Bayer.

0 25866 59236 0

Drug Facts

Active ingredient (in each caplet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Purposes

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - menstrual cramps
 - the common cold
 - temporarily reduces fever
- muscular aches
- headache
- backache
- toothache

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- skin reddening
- rash
- facial swelling
- asthma (wheezing)
- shock
- dizziness
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

DRUG FACTS INFO	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ¹⁴	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ^{**}	8 pt. bold italic [†]	8 pt.
Subheadings	>8 pt.	8 pt.
Body Text	>8 pt.	8 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	1 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Borderline ^{††}	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 30	≤ 30

^{††} Headings are to be at least 2 pts larger than Body Text.
^{†††} Drug Facts Title to be larger than all other type size used in ODP if ODA recommends 2.5 pt. size.

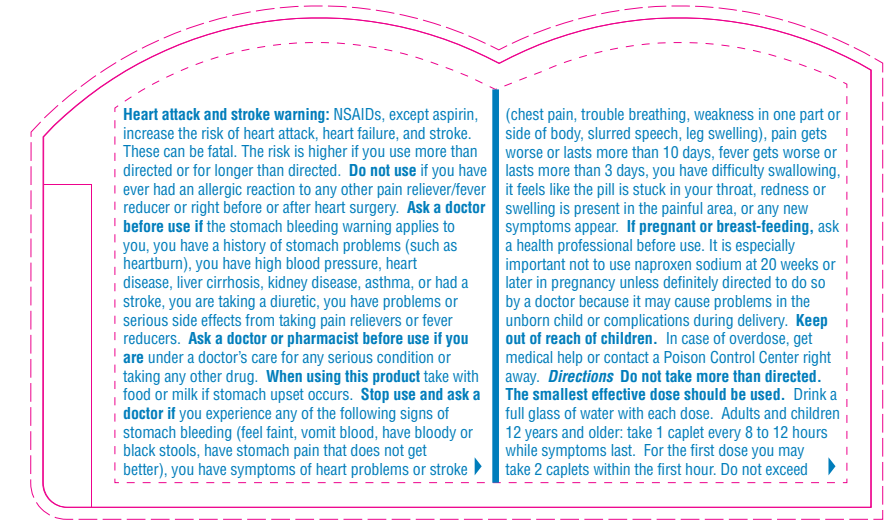
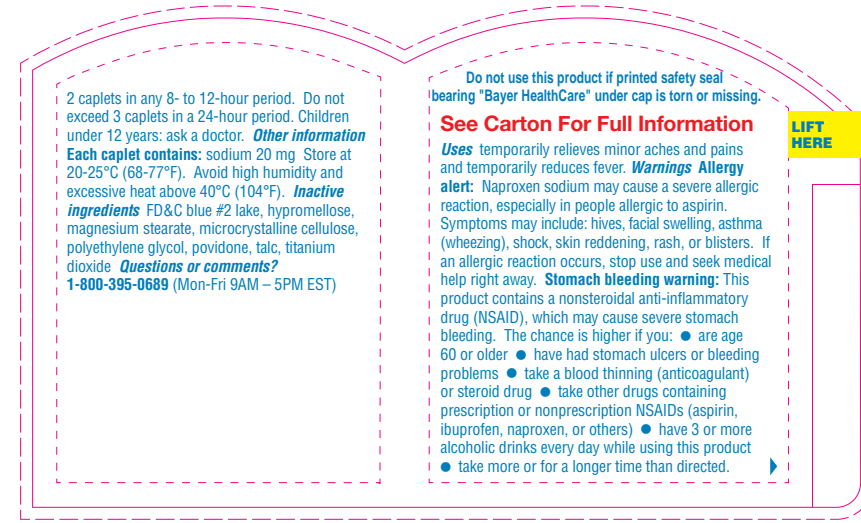
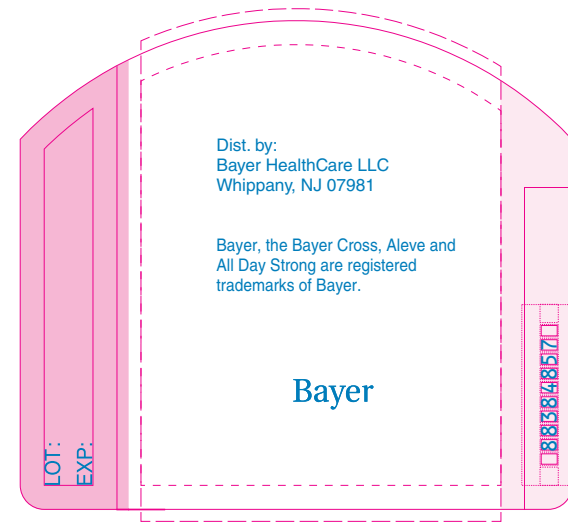


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Actual Size 100%

FDA00292-1



DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	-
Drug Facts Continued	8 pt.	-
Headings†	8 pt-bold italic‡	6 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	5 pt.
Leading	>0.5 pt.	7 pt.
Hair lines	0.5 pt rule	-
Box and Barline†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≤ 39

† Headings are to be at least 2pts larger than Body Text.
 ** Drug Facts Title to be larger than all other type size used in DPP
 † FDA Recommends 2-Spt rule

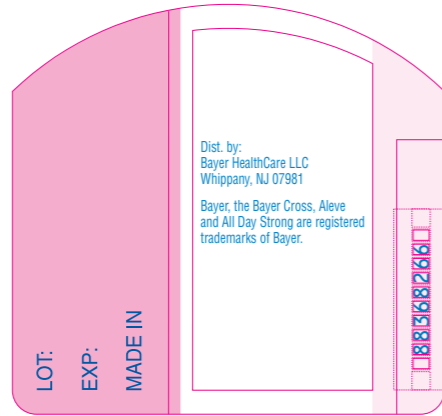


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Actual Size 100%

FDA00272-2



Drug Facts (continued)

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 caplet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 caplets within the first hour
- do not exceed 2 caplets in any 8- to 12-hour period
- do not exceed 3 caplets in a 24-hour period
- ask a doctor

Children under 12 years

Other Information

- each caplet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive Ingredients: FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments? 1-800-368-0000 (MOR-FRI 9AM-5PM EST)

Bayer

Drug Facts

Active ingredient (in each caplet): Naproxen sodium 220 mg

Purpose: Pain reliever/fever reducer

Contains aspirin†

†Bayer HealthCare is a registered trademark of Bayer HealthCare AG, Germany.

123866159226

Drug Facts (continued)

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - headache
 - menstrual cramps
 - toothache
- the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin redness/itching
- facial swelling
- shock
- dizziness
- fainting
- trouble breathing
- trouble swallowing
- trouble talking
- trouble seeing
- trouble hearing
- trouble feeling hot or cold
- trouble feeling hungry or thirsty
- trouble feeling tired or weak
- trouble feeling lightheaded or dizzy
- trouble feeling dizzy or lightheaded
- trouble feeling nauseous or sick to your stomach
- trouble feeling bloated or full
- trouble feeling short of breath
- trouble feeling chest pain or tightness
- trouble feeling numbness or tingling
- trouble feeling weakness in one part or side of body
- trouble feeling slurred speech
- trouble feeling leg swelling

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinner (prescription or steroid drug)
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use ††

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs
- you experience any of the following signs of stomach bleeding:
 - vomit blood
 - feel faint
 - have bloody or black stools
- you have stomach pain that does not get better
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings [†]	8 pt-bold italic [†]	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0.5 pt	0.5 - 0.7 pt
Horizontal lines	0.5 pt rule	0.5 pt
Box and Barlines [†]	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 38	≤39

[†] Headings are to be at least 20% larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP
 † FDA Recommends 2.5pt rule

200%



Actual Size 100%

FDA00373-2

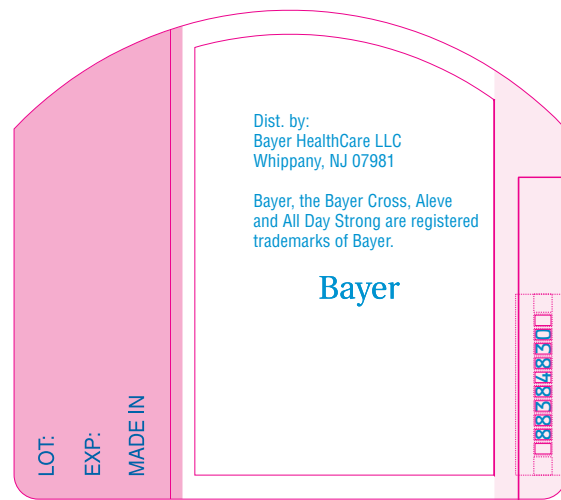


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Actual Size 100%

FDA00307-3



Drug Facts (continued)

Uses

- Temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - headache
 - menstrual cramps
 - the common cold
 - fever
 - temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin redness
- rash
- difficulty breathing
- swelling of the face, lips, tongue, or throat

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or over-the-counter NSAIDs, including aspirin
- take more than 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you have a stomach or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because naproxen may decrease its benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - black or tarry stools
 - blood or blood clots in vomit or back stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- your pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have a stomach or serious side effects from taking this product
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Drug Facts (continued)

Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

OPEN TO READ DRUG FACTS BEFORE USE

LIFT HERE

Drug Facts

Active Ingredient (in each caplet)

Naproxen sodium (naproxen 200 mg) *extended release/fever reducer/anti-inflammatory drug

Purposes

Temporarily relieves minor aches and pains due to: minor pain of arthritis, muscular aches, backache, headache, menstrual cramps, the common cold, fever, temporarily reduces fever.

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, rash, difficulty breathing, swelling of the face, lips, tongue, or throat.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or over-the-counter NSAIDs, including aspirin, take more than 3 or more alcoholic drinks every day while using this product, take more or for a longer time than directed.

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you have a stomach or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because naproxen may decrease its benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - black or tarry stools
 - blood or blood clots in vomit or back stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- your pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have a stomach or serious side effects from taking this product
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Drug Facts (continued)

Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

OPEN TO READ DRUG FACTS BEFORE USE

LIFT HERE

Drug Facts

Active Ingredient (in each caplet)

Naproxen sodium (naproxen 200 mg) *extended release/fever reducer/anti-inflammatory drug

Purposes

Temporarily relieves minor aches and pains due to: minor pain of arthritis, muscular aches, backache, headache, menstrual cramps, the common cold, fever, temporarily reduces fever.

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, rash, difficulty breathing, swelling of the face, lips, tongue, or throat.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: are age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or over-the-counter NSAIDs, including aspirin, take more than 3 or more alcoholic drinks every day while using this product, take more or for a longer time than directed.

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you have a stomach or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- taking aspirin for heart attack or stroke, because naproxen may decrease its benefit of aspirin
- taking any other drug

When using this product

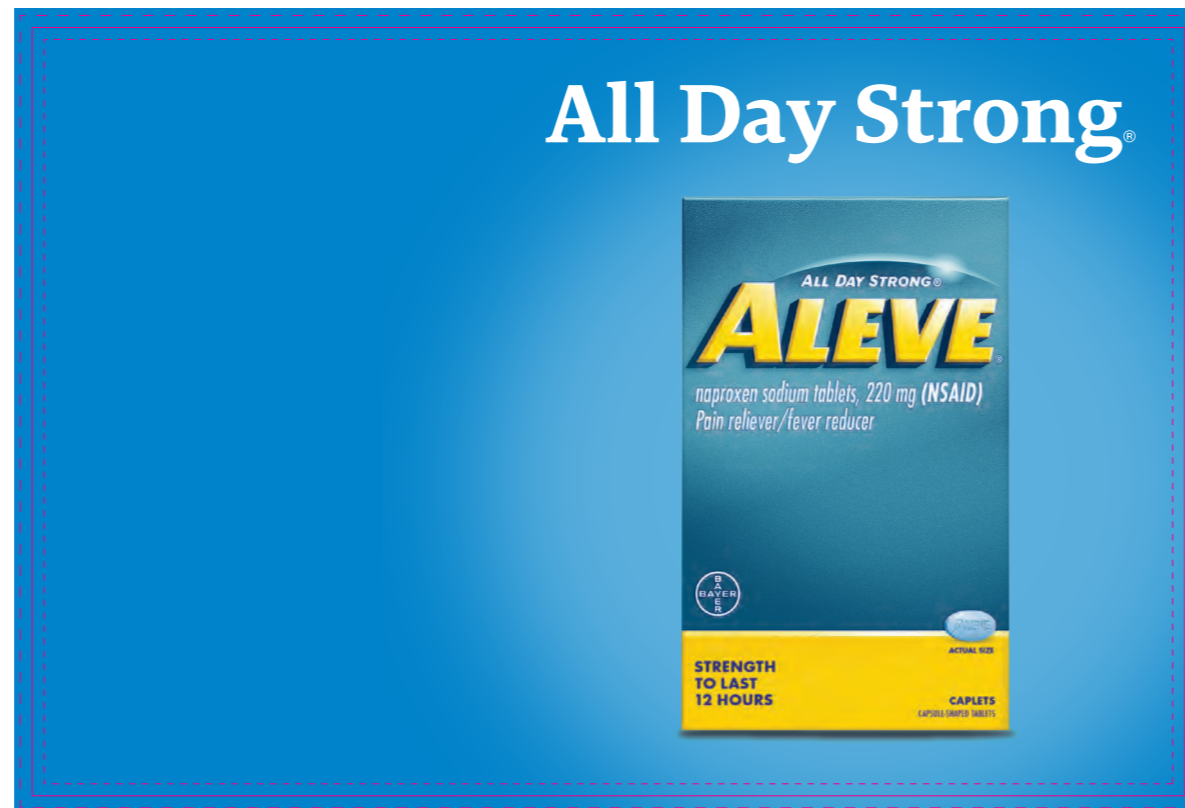
- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - black or tarry stools
 - blood or blood clots in vomit or back stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- your pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have a stomach or serious side effects from taking this product
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt. bold italic [‡]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 33	≤39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP
[‡] FDA Recommendations: 6-pt. rule



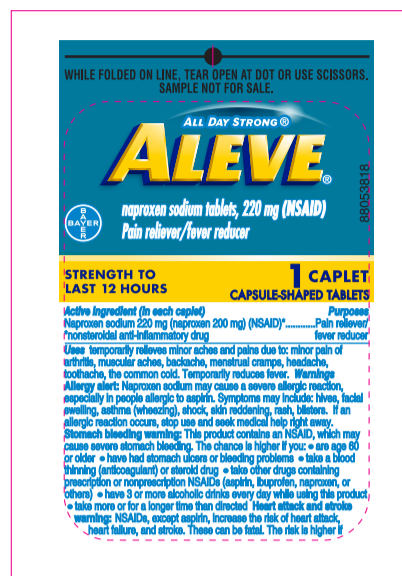
100% SCALE

<p>Drug Facts</p> <p>Active ingredient (in each caplet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> minor pain of arthritis muscular aches menstrual cramps toothache temporarily reduces fever <p>Warnings</p> <p>Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> hives asthma (wheezing) skin reddening <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> are age 60 or older have had stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) have 3 or more alcoholic drinks every day while using this product take more or for a longer time than directed <p>Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p>	<p>Purposes</p> <p>Do not use</p> <ul style="list-style-type: none"> if you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> the stomach bleeding warning applies to you you have a history of stomach problems, such as heartburn you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke you are taking a diuretic you have problems or serious side effects from taking pain relievers or fever reducers <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> under a doctor's care for any serious condition taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin taking any other drug <p>When using this product</p> <ul style="list-style-type: none"> take with food or milk if stomach upset occurs <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> feel faint have bloody or black stools have stomach pain that does not get better you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> chest pain weakness in one part or side of body slurred speech leg swelling pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days you have difficulty swallowing it feels like the pill is stuck in your throat redness or swelling is present in the painful area any new symptoms appear 	<p>Drug Facts (continued)</p> <p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than directed the smallest effective dose should be used drink a full glass of water with each dose <p>Adults and children 12 years and older</p> <ul style="list-style-type: none"> take 1 caplet every 8 to 12 hours while symptoms last for the first dose you may take 2 caplets within the first hour do not exceed 2 caplets in any 8- to 12-hour period do not exceed 3 caplets in a 24-hour period <p>Children under 12 years</p> <ul style="list-style-type: none"> ask a doctor <p>Other information</p> <ul style="list-style-type: none"> each caplet contains: sodium 20 mg store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). <p>Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide</p> <p>Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)</p> <p>DO NOT USE IF POUCH IS TORN OR OPEN.</p> <p>Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer. Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981 ©2020 Bayer C00011565</p>
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100% SCALE

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings†	8 pt-bold italic†	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0.5 pt	0.5 - 0.7 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barlines*	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body text.
** Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2.5pt rule



ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [§]	-
Drug Facts Continued	7 pt [§]	-
Headings	7 pt-bold italic [‡]	4,5 pt
Subheadings	6 pt [§]	4,5 pt
Body Text	6 pt [§]	4,5 pt
Bullets	5 pt	5,5 pt
Headlines	0.5 pt rule	-
Barlines [¶]	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
[§] ICL minimum font size is 4,5 pt.
[‡] < 0,5 pt leading may be used as long as ascenders and descenders do not touch.
[¶] FDA recommends size 2,5 pt type

X |

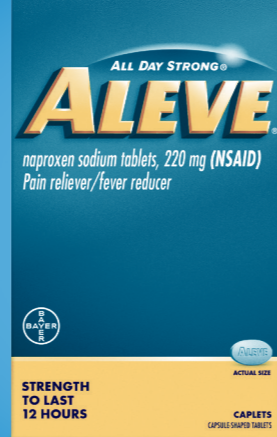
Do not use if pouch is torn or open.

*You use more than directed or for longer than directed.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. **Ask a doctor before use if** • the stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke • you are taking a diuretic • you have problems or serious side effects from taking pain relievers or fever reducers **Ask a doctor or pharmacist before use if you are** • under a doctor's care for any serious condition • taking aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin • taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor if** • you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better) • you have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling) • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • you have difficulty swallowing • it feels like the pill is stuck in your throat • redness or swelling is present in the painful area • any new symptoms appear. **If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions: Do not take more than directed. The smallest effective dose should be used.** Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 2 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. **Other information** Each caplet contains: sodium 20 mg. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Inactive ingredients** FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide. **Questions or comments?** 1-800-368-6889 (Mon-Fri 9AM - 5PM EST).
Dist. by: Bayer HealthCare LLC **MADE IN MEXICO**
Whippany, NJ 07981 88368002

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [§]	-
Drug Facts Continued	7 pt [§]	-
Headings	7 pt-bold italic [§]	4.5 pt
Subheadings	6 pt [§]	4.5 pt
Body Text	6 pt [§]	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-
Characters per inch rule is not applicable to ICL. [§] ICL minimum font size is 4.5 pt. [†] < 0.5 pt leading may be used as long as ascenders and descenders do not touch. [†] FDA recommends size 2.5 pt type		

All Day Strong®




MANUFACTURER'S COUPON EXPIRES 10/31/2022

SAVE \$2.00

ON ANY ONE (1) ALEVE®
20CT. or LARGER
(EXCLUDES ALEVE-D®)

CONSUMER: LIMIT ONE COUPON PER PURCHASE on specified product(s), size(s) and quantity stated. **LIMIT OF 4 EXACT SAME COUPONS PER HOUSEHOLD PER DAY.** You pay any sales tax. Void if copied, sold, transferred, altered, or auctioned.

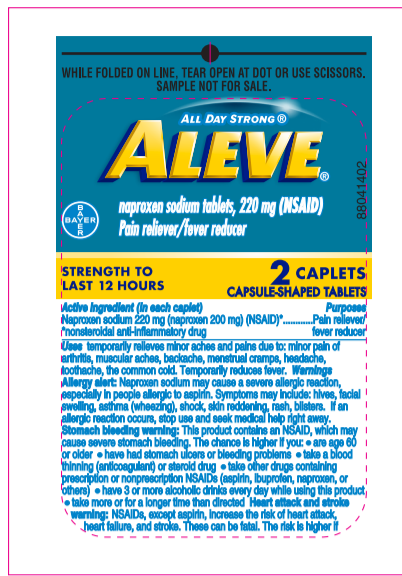
RETAILER: You are authorized to act as our agent and redeem this coupon at face value on the specified product(s). We will reimburse you for the face value of this coupon plus 8¢ if submitted in compliance with the Bayer HealthCare LLC Coupon Redemption Policy, incorporated herein by reference. **USE NOT CONSISTENT WITH THESE TERMS MAY CONSTITUTE FRAUD AND MAY VOID ALL COUPONS SUBMITTED.** Send coupons to: Bayer HealthCare LLC 1355, P.O. Box 880001, El Paso, TX 88588-0001. Cash Value, 1/20th of 1¢. Good only in the U.S.A.

0025866-021836


<p>Drug Facts</p> <p>Active ingredient (in each caplet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> ● temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ● minor pain of arthritis ● muscular aches ● menstrual cramps ● toothache ● temporarily reduces fever ● backache ● headache ● the common cold <p>Warnings</p> <p>Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> ● hives ● asthma (wheezing) ● skin reddening ● facial swelling ● shock ● blisters <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed <p>Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p>	<p>Purposes</p> <ul style="list-style-type: none"> ● if you have ever had an allergic reaction to any other pain reliever/fever reducer ● right before or after heart surgery <p>Do not use</p> <ul style="list-style-type: none"> ● if you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ● you have a history of stomach problems, such as heartburn ● you have problems or serious side effects from taking pain relievers or fever reducers <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ● under a doctor's care for any serious condition ● taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin ● taking any other drug <p>When using this product</p> <ul style="list-style-type: none"> ● take with food or milk if stomach upset occurs <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ● you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> ● feel faint ● have bloody or black stools ● have stomach pain that does not get better ● you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> ● chest pain ● weakness in one part or side of body ● slurred speech ● leg swelling ● pain gets worse or lasts more than 10 days ● fever gets worse or lasts more than 3 days ● you have difficulty swallowing ● it feels like the pill is stuck in your throat ● redness or swelling is present in the painful area ● any new symptoms appear 	<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> ● if you have ever had an allergic reaction to any other pain reliever/fever reducer ● right before or after heart surgery <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> ● the stomach bleeding warning applies to you ● you have a history of stomach problems, such as heartburn ● you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ● you are taking a diuretic ● you have problems or serious side effects from taking pain relievers or fever reducers <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ● under a doctor's care for any serious condition ● taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin ● taking any other drug <p>When using this product</p> <ul style="list-style-type: none"> ● take with food or milk if stomach upset occurs <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ● you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> ● feel faint ● have bloody or black stools ● have stomach pain that does not get better ● you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> ● chest pain ● weakness in one part or side of body ● slurred speech ● leg swelling ● pain gets worse or lasts more than 10 days ● fever gets worse or lasts more than 3 days ● you have difficulty swallowing ● it feels like the pill is stuck in your throat ● redness or swelling is present in the painful area ● any new symptoms appear 	<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> ● do not take more than directed ● the smallest effective dose should be used ● drink a full glass of water with each dose <p>Adults and children 12 years and older</p> <ul style="list-style-type: none"> ● take 1 caplet every 8 to 12 hours while symptoms last ● for the first dose you may take 2 caplets within the first hour ● do not exceed 2 caplets in any 8- to 12-hour period ● do not exceed 3 caplets in a 24-hour period <p>Children under 12 years</p> <ul style="list-style-type: none"> ● ask a doctor <p>Other information</p> <ul style="list-style-type: none"> ● each caplet contains: sodium 20 mg ● store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). <p>Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide</p> <p>Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)</p> <p>DO NOT USE IF POUCH IS TORN OR OPEN. Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer. Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981 ©2021 Bayer C00011513</p> <p style="text-align: right; font-weight: bold;">Bayer</p>
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DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 - 0.7 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP
[†] FDA Recommends 2.5pt. rule



ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt ^a	-
Drug Facts Continued	7 pt ^a	-
Headings	7 pt-bold italic ^b	4.5 pt
Subheadings	6 pt ^a	4.5 pt
Body Text	6 pt ^a	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Barlines ^c	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
^a ICL minimum font size is 4.5 pt.
^b < 0.5 pt leading may be used as long as ascenders and descenders do not touch.
^c FDA recommends size 2.5 pt type

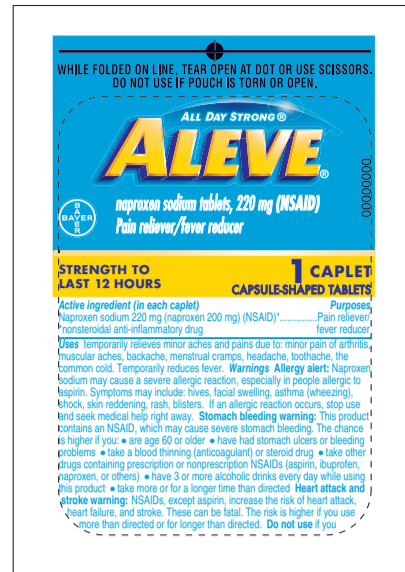
X

Do not use if pouch is torn or open.

• you use more than directed or for longer than directed.
Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. **Ask a doctor before use if** • the stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke • you are taking a diuretic • you have problems or serious side effects from taking pain relievers or fever reducers **Ask a doctor or pharmacist before use if you are** • under a doctor's care for any serious condition • taking aspirin for heart attack or stroke, because naproxen may decrease this benefit • taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor if** • you experience any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better • you have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swe leg) • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • you have difficulty swallowing • it feels like the pill is stuck in your throat • redness or swelling is present in the painful area • any new symptoms appear. **If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions: Do not take more than directed.** The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 caplet every 8 to 12 hours with symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 2 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. **Other information:** Each caplet contains: sodium 20 mg. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Inactive ingredients:** FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, saccharin dioxide. **Questions or comments?** 1-800-395-6689 (Mon-Fri 9AM - 5PM EST)
 Dist. by: Bayer HealthCare LLC **MADE IN MEXICO**
 Whippany, NJ 07981 60207999

ICL (updated 3/29/21)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt ^a	-
Drug Facts Continued	7 pt ^a	-
Headings	7 pt- bold italic ^a	4.5 pt
Subheadings	6 pt ^a	4.5 pt
Body Text	6 pt ^a	4.5 pt
Bullets	5 pt	5 pt
Headlines	0.5 pt rule	-
Bar lines ^f	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
^aICL minimum font size is 4.5 pt.
^b< 0.5 pt leading may be used as long as ascenders and descenders do not touch.
^f FDA recommends size ≥ 5 pt type



Actual Size 100%

FDA00357-5

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt ³	-
Drug Facts Continued	7 pt ⁴	-
Headings	7 pt-bold italic ⁵	4.5 pt
Subheadings	6 pt ⁴	4.5 pt
Body Text	6 pt ⁴	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Barlines ¹	> 0.5 pt rule	-

³Characters per inch rule is not applicable to ICL.
⁴ICL minimum font size is 4.5 pt.
⁵< 0.5 pt leading may be used as long as ascenders and descenders do not touch.
¹ FDA recommends size 2.5 pt type

X |

• **Do not ever take an aspirin product if you have had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. Ask a doctor before use if •** the stomach bleeding warning applies to you • you have a history of stomach problems, such as heartburn • you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke • you are taking a diuretic • you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor or pharmacist before use if you are •** under a doctor's care for any serious condition • taking aspirin for heart attack or stroke, because naproxen may increase this benefit of aspirin • taking any other drug. **When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor if •** you experience any of the following signs of stomach bleeding: feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better • you have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling) • pain gets worse or lasts more than 10 days • fever gets worse or lasts more than 3 days • you have difficulty swallowing • it feels like the pill is stuck in your throat • redness or swelling is present in the painful area • any new symptoms appear. **If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Directions Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 2 years and older: take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 2 caplets in any 8 to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. **Other information** Each caplet contains: sodium 20 mg. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Inactive ingredients** PEG 400, croscarmellose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, croscollon, talc, titanium dioxide. **Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)**
 Div. of: Bayer HealthCare LLC MADE IN MEXICO
 Whisper, NJ 07981 88384784**

ICL Updated 2/27/19		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	-
Drug Facts Continued	7 pt*	-
Headings	7 pt-bold italic ¹	4.5 pt
Subheadings	6 pt*	4.5 pt
Body Text	6 pt*	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines ²	0.5 pt rule	-
Barlines ²	> 0.5 pt rule	-
Characters per inch rule is not applicable to ICL. *ICL minimum font size is 4.5 pt. < 0.5 pt leading may be used as long as ascenders and descenders do not touch. ¹ FDA recommends size 2.5 pt type		



DRUG FACTS INFO (Updated 5/18/20)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>= 8 pt **	8.1 pt
Drug Facts Continued	8 pt	8 pt
Heading [†]	8 pt bold italic [†]	8 pt
Subheadings	>= 8 pt	8 pt
Body Text	>= 8 pt	8 pt
Bullets	8 pt	12 pt
Leading	>= 0.5 pt	0.5 pt
Min size	>= 0.5 pt	0.5 pt
Box and Barline ^{††}	>= 0.5 pt min	0.5 pt
Characters Per Inch	No more than 20	>20

[†] Heading and 12 pt to be used only when the box is larger than 100 mm.
^{††} Drug Facts Title to be larger than all other text and used in 100% FFD requirements of 20 pt min.



Bayer HealthCare Bayer HealthCare Bayer HealthCare
Bayer HealthCare Bayer HealthCare Bayer HealthCare

Drug Facts

Active ingredient (in each tablet) **Purposes**

Naproxen sodium 220 mg (naproxen 200 mg)
(NSAID)..... Pain reliever/fever reducer
Nonsteroidal anti-inflammatory drug

Uses Temporarily relieves minor aches and pains due to:
● backache ● muscular aches ● minor pain of arthritis
● menstrual cramps ● headache ● toothache
● the common cold

Warnings **Alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ● hives ● facial swelling ● asthma (wheezing) ● shock ● skin redness ● rash ● dizziness. If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause serious stomach bleeding. The chance is higher if you: ● are age 60 or older ● have had stomach ulcers or bleeding problems ● take a blood thinning (anticoagulant) or steroid drug ● take other drugs containing naproxen, ibuprofen, naproxen, non-steroidal NSAIDs (aspirin, butabren, naproxen, or others) ● have 3 or more alcoholic drinks every day while using this product ● take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use ● If you have ever had an allergic reaction to any other pain reliever/fever reducer ● right before or after heart surgery

Ask a doctor before use if ● you have a history of stomach warning applies to you ● you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ● you are taking a diuretic ● you have problems of liver enzymes ● you have problems of liver enzymes

COO01511



0 417491 0
NDC 0174-9100-01

LOT
EXP
MADE IN

ALEVE
All Day Strength
BACK & MUSCLE PAIN
Naproxen sodium tablets, 220 mg (Naproxen)
Pain reliever/fever reducer

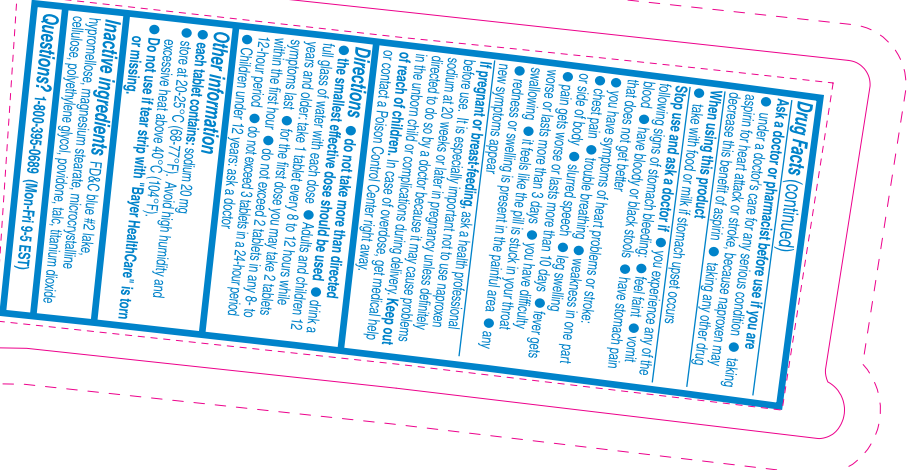
for temporary relief of minor
back and muscle aches and pains

10 TABLETS
STRENGTH TO
LAST 12 HOURS

Do not use if seal strip with Bayer
HealthCare is torn or missing.

OPEN HERE TO VIEW TABLETS
PRODUCT INFORMATION

Dr. Dr. Bayer HealthCare LLC
Whispery, NJ 07881
Bayer and All Day
Strength are registered
trademarks of Bayer.



Drug Facts (continued)

Ask a doctor or pharmacist before use if you are
● under a doctor's care for any serious condition ● taking
aspirin for heart attack or stroke because naproxen may
decrease the benefit of aspirin ● taking any other drug
When using this product ● taking any other drug

Stop use and ask a doctor if ● you experience any of the
following signs of stomach bleeding ● feel faint ● vomit
● have bloody or black stools ● have stomach pain
● you have symptoms of heart problems or stroke:
● chest pain ● trouble breathing ● weakness in one part
of side of body ● slurred speech ● leg swelling
● pain or gas more than 3 days from 10 days ● fever, gas
● redness or swelling is present in the painful area ● any
new symptoms appear

If pregnant or breast-feeding, ask a health professional
before use. It is especially important not to use naproxen
sodium at 20 weeks or later in pregnancy, or less often
in the unborn child, because it may cause problems
of reach of children. In case of overdose, get medical help
or contact a Poison Control Center right away.

Directions ● do not take more than directed
● the smallest effective dose should be used ● drink a
full glass of water with each dose ● Add to a glass of water
years and older: take 1 tablet every 8 to 12 hours and children 12
symptoms last ● for the first dose you may take 2 tablets
within the first hour ● do not exceed 2 tablets in any 8- to
12-hour period ● do not exceed 3 tablets in a 24-hour period
● Children under 12 years: ask a doctor

Other information
● each tablet contains: sodium 20 mg
● store at 20° to 25° C (68° to 77° F). Avoid high humidity and
excessive heat above 40° C (104° F).
● Do not use if seal strip with Bayer HealthCare is torn
or missing.

Inactive ingredients: FD&C Blue #2 lake
hydroxytoluene, magnesium stearate, microcrystalline
cellulose, polyethylene glycol, polyethylene glycol, titanium dioxide

Questions? 1-800-955-0889 Mon-Fri 9-5 EST

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt.-bold (ita it ^h)	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	6-6.5 pt.
Hairlines	0.5 pt. rule	.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤ 39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† FDA Recommends 2.5pt. rule

88368118





002651998520



Do not use if carton is open or if foil seal imprinted with Bayer HealthCare™ on bottle opening is missing or broken.

Direct To: Bayer HealthCare LLC, 1000 N. 17th St., P.O. Box 117, Wallingford, CT 06495

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Drug Facts (continued)

● take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

ALL DAY STRONG

ALEVE

BACK & MUSCLE PAIN

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer



for temporary relief of minor back and muscle aches and pains

ACTUAL SIZE

24 TABLETS

Drug Facts

Active ingredient (in each tablet)
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* Pain reliever/fever reducer

Purposes
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - backache
 - minor pain of arthritis
 - menstrual cramps
 - toothache
- muscular aches
- headache
- the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product.

8118



LOT EXP MADE IN Bayer



DRUG FACTS INFO (updated 5/18/16)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt.-bold italic‡	8 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 - 0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

† Headings are to be at least 2pts larger than Body text.
** Drug Facts Title to be larger than all other type size used in ODP
‡ FDA Recommends 2.5pt rule

88368126



Do not use if carton is open or if foil seal imprinted with Bayer HealthCare on bottle opening is missing or broken

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor

Drug Facts (continued)

because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period
- ask a doctor

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981
Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.

Bayer

Drug Facts

Active ingredient (in each tablet)
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*... Pain reliever/fever reducer

Purposes
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - backache
 - muscular aches
 - minor pain of arthritis
 - menstrual cramps
 - headache
 - toothache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

LOT EXP MADE IN



DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold/italic [‡]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 pt. - 0.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP.
[‡] FDA Recommends 2.5pt rule.

88368088



Do not use if carton is open or if foil seal is missing or broken.
Bayer HealthCare on bottle opening is missing or broken.

**GLUE ASSIST AREA
NO VARNISH**

NO VARNISH - GLUE AREA

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

8808

QUIET ZONE

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

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Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981

**LOT
EXP**

MADE IN

ALL DAY STRONG

ALEVE

BACK & MUSCLE PAIN

naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

for temporary relief of
minor back and muscle
aches and pains

**STRENGTH
TO LAST
12 HOURS**

ACTUAL SIZE

**90
TABLETS**




**GLUE ASSIST AREA
NO VARNISH**

QUIET ZONE



QUIET ZONE

**GLUE ASSIST AREA
NO VARNISH**

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{1*}	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ²	8 pt.-bold italic ³	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	6.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines ⁴	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤ 39

¹ Headings are to be at least 2pts larger than Body Text.
² Drug Facts Title to be larger than all other type size used in DPP
³ FDA Recommends 2.5pt rule

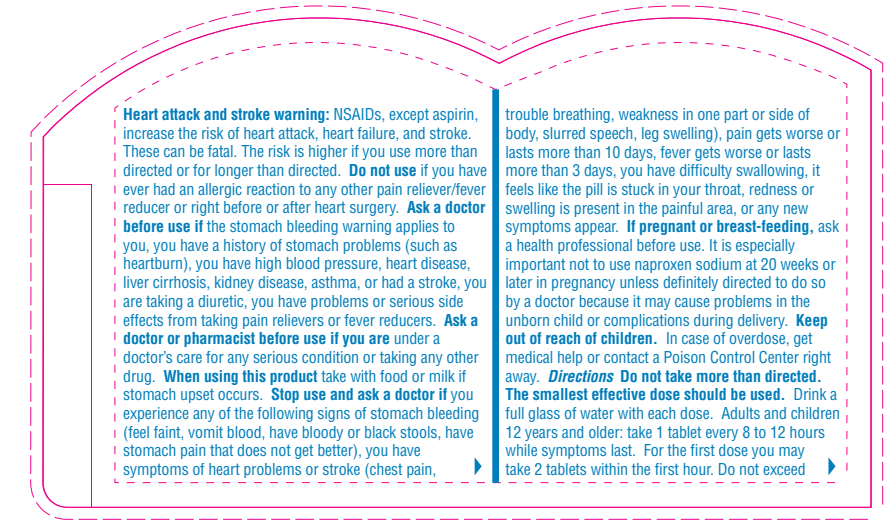
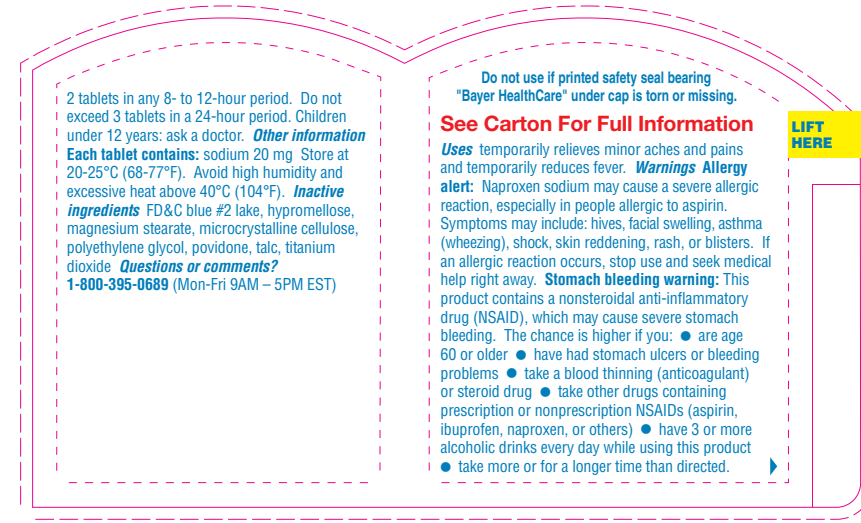
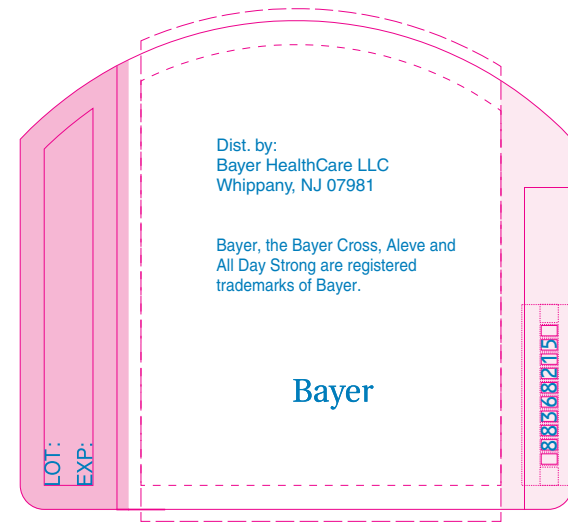


200%



Actual Size 100%

FDA00277-3



DRUG FACTS INFO: (Modified Format – updated 3/1/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt-bold italic*	6 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	6 pt	12 pt
Leading	≥0 pt	1 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DPP
† Box Bar line may be omitted and color contrast used to highlight Drug Facts Info

88369998

ALL DAY STRONG®
ALEVE®
BACK & MUSCLE PAIN
naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

for temporary relief of
minor back and muscle
aches and pains

**STRENGTH
TO LAST
12 HOURS**

**200
TABLETS**

8 6 6 6



LOT
dX3
MADE IN
NI 33VW

ALL DAY STRONG®
ALEVE®
BACK & MUSCLE PAIN
naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

for temporary relief of
minor back and muscle
aches and pains

**STRENGTH
TO LAST
12 HOURS**

**200
TABLETS**



LOT
dX3
MADE IN
NI 33VW

ALL DAY STRONG®
ALEVE®
BACK & MUSCLE PAIN
naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

for temporary relief of
minor back and muscle
aches and pains

**STRENGTH
TO LAST
12 HOURS**

**200
TABLETS**



Drug Facts (continued)

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Directions

- do not take more than directed
- drink a full glass of water with each dose
- the smallest effective dose should be used

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours with symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 3 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

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Do not use if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

Bayer

Drug Facts

Active ingredient (in each tablet) Naproxen sodium 220 mg (Naproxen 500 mg) (NSAID)*

Purposes Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - backache
 - muscular aches
 - minor pain of arthritis
 - menstrual cramps
 - headache
 - toothache
 - the common cold
 - temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash

Warnings

- **Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
 - are age 60 or older
 - have had stomach ulcers or bleeding problems
 - take a blood thinning (anticoagulant) or steroid drug
 - take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
 - have 3 or more alcoholic drinks every day while using this product
 - take more or for a longer time than directed
- **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

DRUG FACTS INFO (Updated 5/19/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	≥8 pt.**	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold table*	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Horizontal Lines	0.5 pt. rule	0.5 pt.
Box and Barlines†	≥0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 35	≤33

* Headings are to be at least Size 8, larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP.
† FDA Recommendations 2.5pt. rule



DRUG FACTS INFO (Updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold italic*	8 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	0.5 pt.
Headlines	0.5 pt rule	0.5 pt.
Box and Barlines†	>0.5 pt rule	2.5 pt.
Characters Per Inch:	No more than 35	≤35

* Headings are to be at least Size larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP.
† FDA Recommends 2.5pt rule

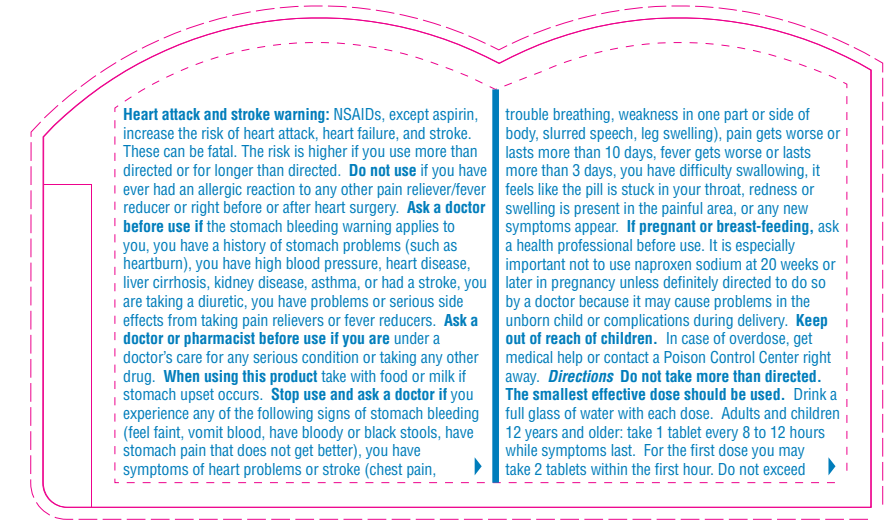
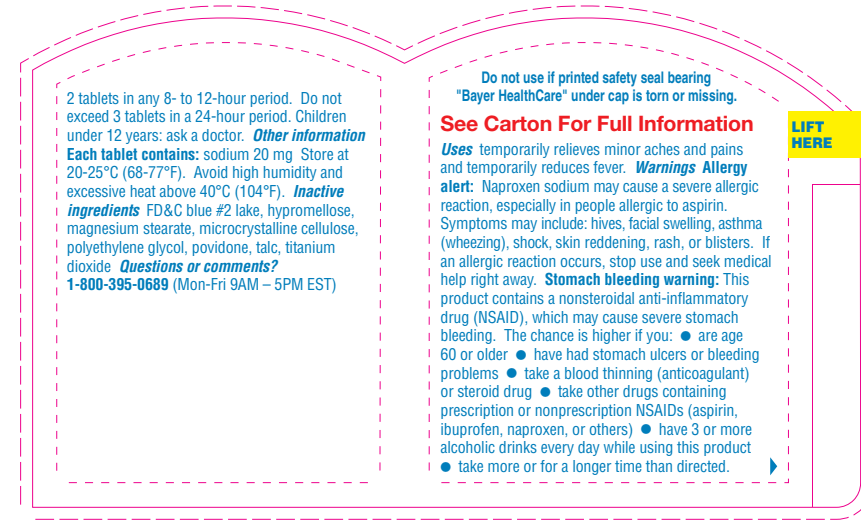
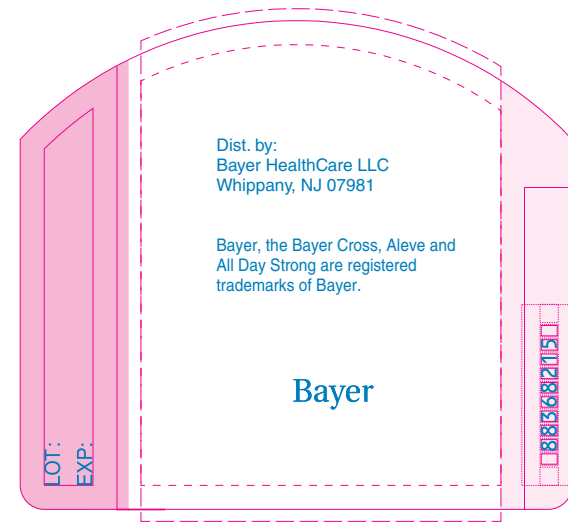


200%



Actual Size 100%

FDA00299-1



DRUG FACTS INFO: (Modified Format - updated 3/1/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt-bold italic*	6 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	6 pt	12 pt
Leading	≥0 pt	1 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP
† Box Bar line may be omitted and color contrast used to highlight Drug Facts Info



Actual Size 100%

FDA47174-1

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt.-bold italic*	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 20% larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DDP.
† FDA Recommends 2.5pt. rule.



88368371

Do not use if carton is open or if foil seal imprinted with Bayer HealthCare® on bottle opening is missing or broken.

By: The Bayer Cross, Above and All Day Strong are registered trademarks of Bayer.
Mylan, Mylan Pharmaceuticals LLC
Mylan, NJ 07951

Drug Facts (continued)

● take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

ALL DAY STRONG®

ALEVE®

HEADACHE PAIN

naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

for temporary relief of headache pain



STRENGTH TO LAST 12 HOURS

24 TABLETS

ACTUAL SIZE

Drug Facts (continued)

Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

LOT EXP MADE IN Bayer

Drug Facts

Active ingredient (in each tablet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*Pain reliever/fever reducer

Purposes

- temporarily relieves minor aches and pains due to:
 - headache
 - minor pain of arthritis
 - muscular aches
 - menstrual cramps
 - backache
 - the common cold
 - toothache
 - temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	6.2 - 6.5 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	<39

[†] Headings are to be at least 20% larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP
[†] FDA Recommends 2.5pt. rule

88368452



Do not use if carton is open or if foil seal imprinted with Bayer Healthcare on bottle opening is missing or broken.

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk. If stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981
Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.

Bayer

Drug Facts

Active ingredient (in each tablet)	Purposes
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*	Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - backache
 - toothache
- temporarily reduces fever
- minor pain of arthritis
- menstrual cramps
- the common cold

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

LOT EXP MADE IN



DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0 - 0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2xts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP.
† FDA Recommends 2.5pt. rule



88368355

Do not use if carton is open or if seal is missing or broken.

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years:

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients: FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon-Fri 9AM-5PM EST)

Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.

Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981

Drug Facts

Active ingredient (in each tablet)
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*. Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Purposes

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - backache
 - toothache
 - the common cold
 - temporarily reduces fever
- minor pain of arthritis
- menstrual cramps

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - backache
 - toothache
 - the common cold
 - temporarily reduces fever
- minor pain of arthritis
- menstrual cramps

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin redness
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

LOT EXP MADE IN



9938

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines [‡]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤ 39

[†] Headings are to be at least 20% larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in ODP.
[‡] FDA Recommends 2.5pt. rule.



88384946

Do not use if carton is open or if foil seal imprinted with Bayer HealthCare on bottle opening is missing or broken.

Drug Facts (continued)

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?
1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981
Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.

Bayer

Drug Facts

Active ingredient (in each tablet)
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*..... Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

Purposes

- temporarily relieves minor aches and pains due to:
 - headache
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - toothache
 - the common cold
- temporarily reduces fever

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - toothache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- asthma (wheezing)
- skin reddening
- blisters
- facial swelling
- shock
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

for temporary relief of headache pain




STRENGTH TO LAST 12 HOURS

175 TABLETS

LOT EXP MADE IN



DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	9 pt
Drug Facts Continued	8 pt	8 pt
Headings [†]	8 pt-bold italic [†]	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0.5 pt	6.8 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barlines [‡]	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 30	≤30

[†] Headings are to be at least 20% larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP.
[‡] FDA Recommends 2.5pt rule.



200%



Actual Size 100%

FDA00336-2

See Carton for Full Information

Warnings: Allergy alert. Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin reddening, rash, or blisters. If an allergic reaction occurs, stop use and seek medical help right away. **Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

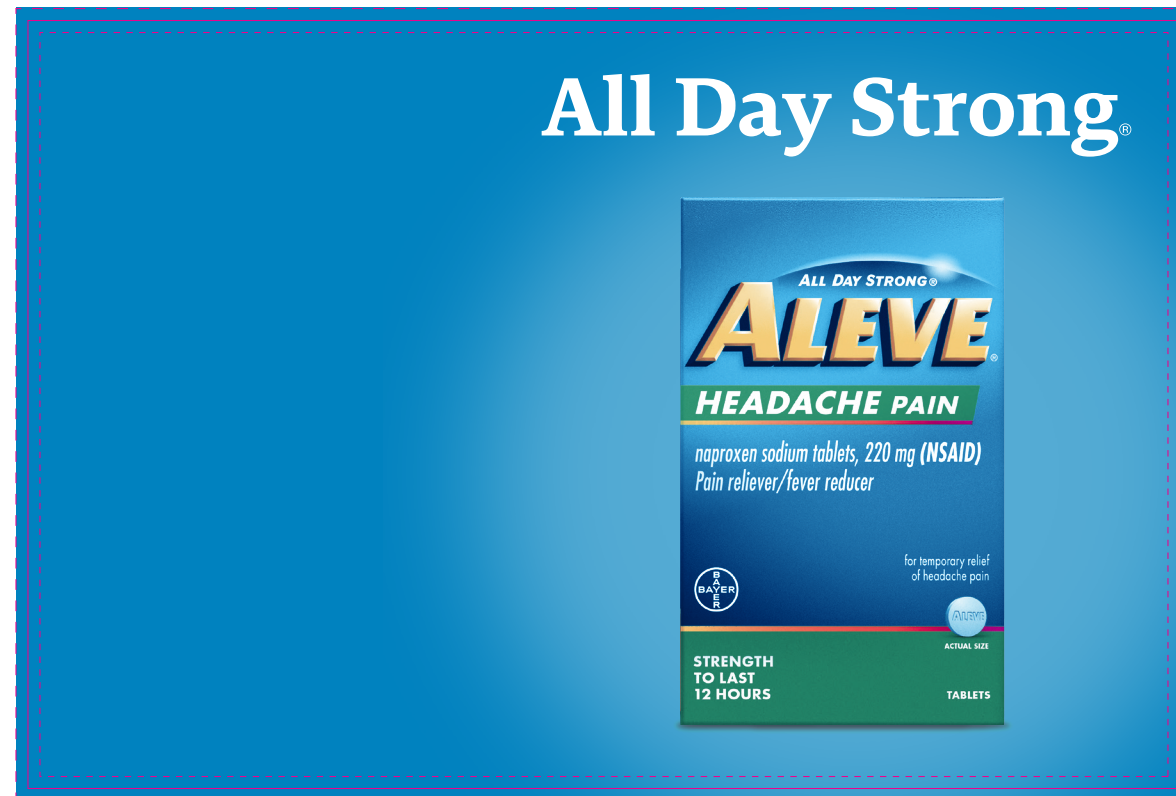
• take more or for a longer time than directed. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed. **Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer or right before or after heart surgery. **Ask a doctor before use** if the stomach bleeding warning applies to you, you have a history of stomach problems (such as heartburn), you have high blood pressure, heart disease, liver cirrhosis, or kidney disease, asthma, or had a stroke, you are taking a diuretic, you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor or pharmacist before use** if you are under a doctor's care for any serious condition or taking any other drug. **When using this product** take with food or milk if stomach upset occurs. **Stop use and ask a doctor** if you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have a thick, white, swollen throat, it feels like the pill is stuck in your throat, redness or swelling is present in the painful area, or any new symptoms appear. **If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions: Do not take more than directed. The smallest effective dose should be used.** Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 tablet every 8 to 12 hours while symptoms last. For the first dose you may take 2 tablets within the first hour. Do not exceed 2 tablets in any 8- to 12-hour period. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor. Store at 20-25°C (68-77°F). Avoid high humid and excessive heat above 40°C (104°F). **Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)**

Dist. by
Bayer HealthCare LLC
Whippany, NJ 07981

8 8 3 8 4 9 5 4

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [‡]	-
Drug Facts Continued	7 pt [‡]	-
Headings	7 pt-bold italic [‡]	4.5 pt
Subheadings	6 pt [‡]	4.5 pt
Body Text	6 pt [‡]	4.5 pt
Bullets	5 pt	8 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
[‡]ICL minimum font size is 4.5 pt.
[†] 0.5 pt leading may be used as long as ascenders and descenders do not touch.
[†] FDA recommends size 2.5 pt type



<p>Drug Facts</p> <p>Active ingredient (in each tablet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p>Purposes</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> headache minor pain of arthritis backache toothache temporarily reduces fever muscular aches menstrual cramps the common cold <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> headache minor pain of arthritis backache toothache temporarily reduces fever muscular aches menstrual cramps the common cold <p>Warnings</p> <p>Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> hives asthma (wheezing) skin reddening facial swelling shock rash blisters <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> are age 60 or older have had stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug take other drugs containing prescription or nonprescription NSAIDs (aspirin, bupropion, naproxen, or others) have 3 or more alcoholic drinks every day while using this product take more or for a longer time than directed <p>Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p>	<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> if you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> the stomach bleeding warning applies to you you have a history of stomach problems, such as heartburn you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke you are taking a diuretic you have problems or serious side effects from taking pain relievers or fever reducers <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> under a doctor's care for any serious condition taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin taking any other drug <p>When using this product</p> <ul style="list-style-type: none"> take with food or milk if stomach upset occurs <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> feel faint have bloody or black stools have stomach pain that does not get better chest pain weakness in one part or side of body slurred speech leg swelling pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days you have difficulty swallowing it feels like the pill is stuck in your throat redness or swelling is present in the painful area any new symptoms appear 	<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than directed the smallest effective dose should be used drink a full glass of water with each dose <p>Adults and children 12 years and older</p> <ul style="list-style-type: none"> take 1 tablet every 8 to 12 hours while symptoms last for the first dose you may take 2 tablets within the first hour do not exceed 2 tablets in any 8- to 12-hour period do not exceed 3 tablets in a 24-hour period <p>Children under 12 years</p> <ul style="list-style-type: none"> ask a doctor <p>Other information</p> <ul style="list-style-type: none"> each tablet contains: sodium 20 mg store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). <p>Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide</p> <p>Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)</p> <p>DO NOT USE IF POUCH IS TORN OR OPEN.</p> <p>Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer. Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981 ©2020 Bayer C00011564</p>
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DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{**}	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt.-bold italic [‡]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 - 0.7 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

[†] Headings are to be at least 2pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP
[†] FDA recommends 2.5pt rule



ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [§]	-
Drug Facts Continued	7 pt [§]	-
Headings	7 pt-bold italic [§]	4.5 pt
Subheadings	6 pt [§]	4.5 pt
Body Text	6 pt [§]	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-
Characters per inch rule is not applicable to ICL. § ICL minimum font size is 4.5 pt. < 0.5 pt leading may be used as long as ascenders and descenders do not touch. † FDA recommends size 2.5 pt type		

X |

Do not use if pouch is torn or open.

than directed or for longer than directed. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. **Ask a doctor before use if**

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product take with food or milk if stomach upset occurs. **Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding (feel faint, vomit blood, have bloody or black stools, have stomach pain that does not get better)
- you have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling)
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

Pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Directions** Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 tablet every 8 to 12 hours while symptoms last. For the first dose you may take 2 tablets within the first hour. Do not exceed 2 tablets in any 8- to 12-hour period. Do not exceed 3 tablets in a 24-hour period. Children under 12 years: ask a doctor. **Other information** Each tablet contains sodium 20 mg. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Inactive ingredients** FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide. **Questions or comments?** 1-800-368-0889 (Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC
Whippany, NJ 07981

MADE IN INDIA
88368029

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt ^a	-
Drug Facts Continued	7 pt ^a	-
Headings	7 pt-bold italic ^a	4.5 pt
Subheadings	6 pt ^a	4.5 pt
Body Text	6 pt ^a	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Barlines [†]	> 0.5 pt rule	-

Characters per inch rule is not applicable to ICL.
^aICL minimum font size is 4.5 pt.
 < 0.5 pt leading may be used as long as ascenders and descenders do not touch.
[†] FDA recommends size 2.5 pt type

SOFT GRIP® ARTHRITIS CAP
MADE IN USA
LOT

ALL DAY STRONG®
ALEVE

Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

SOFT GRIP® ARTHRITIS CAP
ALL DAY STRONG®
ALEVE

naproxen sodium tablets, 220 mg (NSAID)
Pain reliever/fever reducer

THIS PACKAGE IS CHILD-RESISTANT

ALEVE
ACTUAL SIZE

40 GELCAPS
GELATIN COATED CAPSULE-SHAPED TABLETS

STRENGTH TO LAST 12 HOURS

Drug Facts (continued)

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients D&C yellow #10 aluminum lake, edetate disodium, edible ink, FD&C blue #1, FD&C yellow #6 aluminum lake, gelatin, glycerin, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, talc, titanium dioxide

Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)

Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981

Bayer, the Bayer Cross, Aleve, All Day Strong and Soft Grip are registered trademarks of Bayer.

Bayer

Drug Facts

Active ingredient (in each tablet)
Naproxen sodium 220 mg (naproxen 200 mg (NSAID))
Pain reliever/fever reducer
nonsteroidal anti-inflammatory drug

Purposes

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - backache
 - headache
 - the common cold
 - temporarily reduces fever
 - muscular aches
 - menstrual cramps
 - toothache

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

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0 25866 59234 6

DRUG FACTS INFO (updated 5/19/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt.-bold italic‡	8 pt.
Subheadings	≥5 pt.	6 pt.
Body Text	≥5 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	6.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 35	≤ 39

† Headings are to be at least 6 pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DFP.
‡ FDA Recommends 2.5 pt. rule

LOT
EXP
MADE IN

ALL DAY STRONG

 Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.

Drug Facts (continued)

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing
- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose you may take 2 tablets within the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years

- ask a doctor

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients D&C yellow #10 aluminum lake, edelate disodium, edible ink, FD&C blue #1, FD&C yellow #6 aluminum lake, gelatin, glycerin, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, talc, titanium dioxide

Questions or comments? 1-800-395-0689
(Mon-Fri 9AM-5PM EST)

Dist. by:
Bayer HealthCare LLC
Whippany, NJ 07981

Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.

Bayer

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)[†].....Pain reliever/fever reducer[†]
*nonsteroidal anti-inflammatory drug

Purposes

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - headache
 - toothache
 - the common cold
- temporarily reduces fever

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - headache
 - toothache
 - the common cold
- temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.



STRENGTH TO LAST 12 HOURS
 ACTUAL SIZE
90 GELCAPS
 GELATIN COATED CAPSULE-SHAPED TABLETS

LOT#99688
LOT#8





0 25866 159355 8



DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. **	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	8 pt. bold italic [†]	8 pt.
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	6.5 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines [†]	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 29	≤ 39

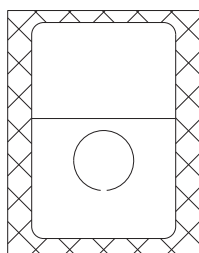
[†] Headings are to be at least 20% larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP.
[†] FDA Recommends 2.5pt. rule

200%



Actual Size 100%

FDA00288-3



UP TO 12 Hours of Menstrual Pain Relief

MENSTRIDOL
Naproxen Sodium Tablets, 220 mg
Pain Reliever/Fever Reducer (NSAID)

from the makers of **Midol**

TEMPORARILY RELIEVES
CRAMPS | BACKACHE | HEADACHE
MINOR

20 CAPLETS*
*PILL-SHAPED TABLETS

Do not use if blister is cut or broken.

Dist. by:
Bayer HealthCare LLC
Whispery, IN 47381
Bayer, the Bayer Cross, Midol
and Menstridol are registered
trademarks of Bayer.

LOT & EXP
CODE AREA

Made in

Lot
Exp

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs.

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have difficulty swallowing

Drug Facts (continued)

- it feels like the pill is stuck in your throat
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than directed
- the smallest effective dose should be used
- drink a full glass of water with each dose

under 12 years ask a doctor

Drug Facts (continued)

adults and children 12 years and older

- take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 2 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period.

Other information

- each caplet contains: sodium 20 mg

Drug Facts (continued)

- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients

FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions? 1-800-331-4536

Drug Facts

Active ingredient (in each caplet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*

Purposes Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - menstrual cramps
 - muscle aches
 - headache
 - backache
 - minor pain of arthritis
 - toothache
 - the common cold
- temporarily reduces fever

Drug Facts (continued)

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day

Drug Facts (continued)

while using this product

- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

Drug Facts (continued)

Other information

each caplet contains: sodium 20 mg

Actual Size 100%

FDA00245-3

DRUG FACTS INFO <small>(updated 5/18/18)</small>		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	9 pt
Drug Facts Continued	8 pt	8 pt
Headings†	8 pt bold italic‡	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0.5 pt	0.5 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines†	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

** Headings are to be at least 2pts larger than Body Text.
†† Drug Facts Title to be larger than all other type size used in DFP
‡ FDA Recommends 2.5pt rule

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

VALERIE S PRATT
03/10/2022 11:53:09 AM