

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

Drug Facts
Naproxen sodium 250 mg (naproxen 200 mg) (NSAID) ... Pain reliever/fever reducer

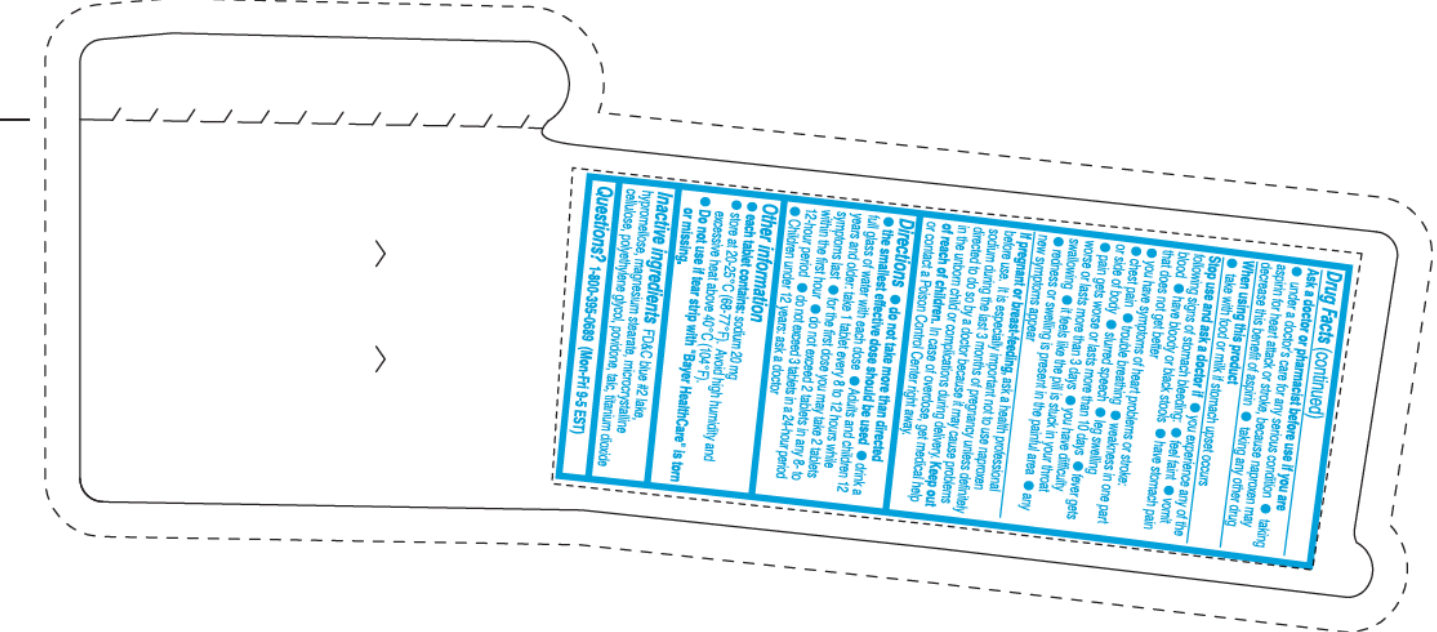
Warnings Always alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, eye use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe GI or other... have had stomach ulcers or bleeding problems or stomach or other drugs containing iron, ibuprofen, naproxen, non-steroidal anti-inflammatory drugs every day or others) ● take 3 or more tablets 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 or kidney disease, asthma, or had a stroke ● you are taking a diuretic, aspirin, have problems or serious side effects from taking pain relievers or fever reducers



Drug Facts (continued)
Ask a doctor or pharmacist before use if you are pregnant or breastfeeding, or if you are taking other drugs. Do not use if you are allergic to any of the ingredients listed below. Stop use and ask a doctor if you experience any of the following symptoms: ● you have ever had a severe allergic reaction to any other drug ● you have ever had a severe allergic reaction to any other drug ● you have ever had a severe allergic reaction to any other drug

Directions ● do not take more than directed ● all doses of water ● take 1 tablet 2 times a day with meals ● for the first 2 days take 2 tablets 12 hours apart ● do not exceed 3 tablets in any 8- to 12-hour period ● do not exceed 2 tablets in any 8- to 12-hour period ● do not exceed 3 tablets in 24-hour period ● Children under 12 years: ask a doctor

Other Information
● each tablet contains: naproxen 250 mg, sodium 200 mg, 250 mg ● store at 20-25°C (68-77°F); excursions permitted to 15°-30°C (59°-86°F) ● do not use if new strip with "Bayer HealthCare" is torn or missing

Inactive Ingredients FDIC blue #2 ink, hypromellose, hydroxypropyl methylcellulose, polyethylene glycol, polyethylene glycol, titanium dioxide

Questions? 1-800-398-0888 (Mon-Fri 9-5 EST)

Actual Size 100%

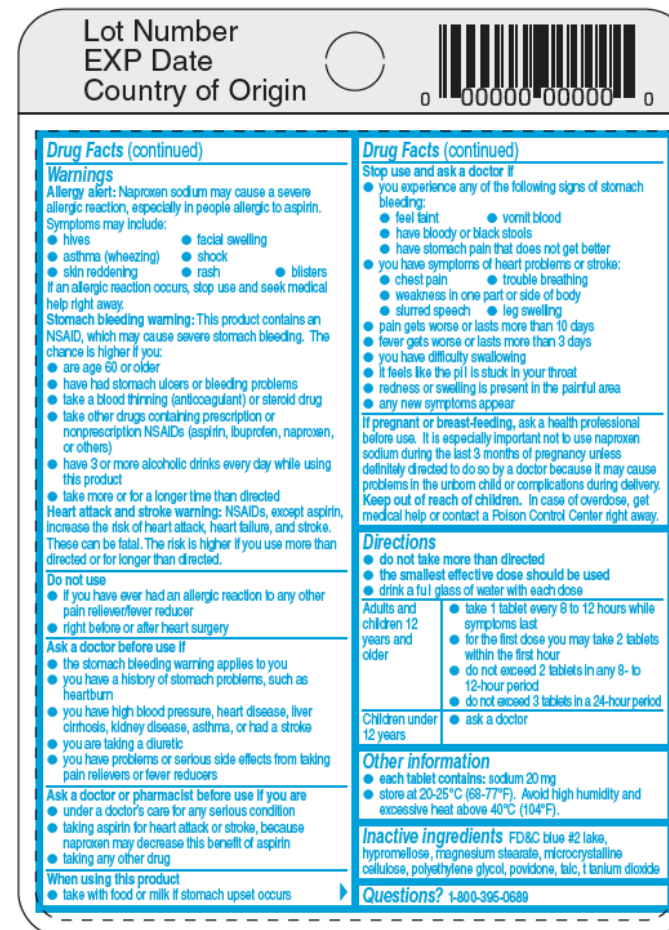
FDA00406-3

DRUG FACTS INFO: (Modified Format - updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	8.1 pt
Drug Facts Continued	7 pt	8 pt
Headings*	7 pt-bold italic*	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0 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 2 pts larger than Body text
† Box Bar lines may be omitted and color contrast used to highlight Drug Facts info



FRONT



BACK

Actual Size 100%

FDA00305-2

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 DPP.
† 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



Actual Size 100%

FDA00308-1

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.
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 types used in DFP
 ‡ FDA Recommends 2.5pt rule



200%



Actual Size 100%

FDA00403-2

Do not use if the seal
 implanted with Bayer HealthCare
 on both opening is missing or broken.
 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), stomach, skin redness, rash, or
 dizziness. 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 65 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. 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 (red hair, vomit blood, have
 bloody or black stools, have stomach pain that does

Do 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 2 pain or fever gets
 worse. If pregnant or breast-feeding, ask a health
 professional before use. Keep out of reach of children. In
 case of overdose, get medical help or contact a Poison Control
 Center right away. Directions: Adults and children 12 years and
 older: take 1 tablet with water every 8 to 12 hours while symptoms last.
 For the first dose you may take 2 tablets within the first hour.
 Do not exceed 3 tablets in a 24-hour period. Children under
 12 years: ask a doctor. Questions or comments? 1-800-395-6689
 ©2019 Bayer HealthCare LLC, Whippany, NJ 07981

ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	NA
Drug Facts Continued	7 pt*	NA
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	NA
Barlines†	> 0,5 pt rule	NA

Characters per inch rule is not applicable to ICL.
 *ICL minimum font size is 4,5 pt.
 † FDA recommends size 2,5 pt type



Actual Size 100%

FDA00301-2

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 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

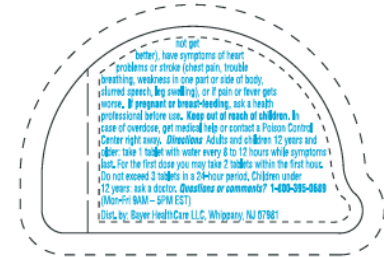
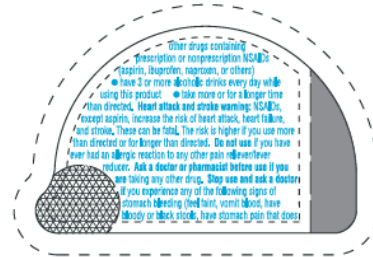


200%



Actual Size 100%

FDA00404-3



ICL (updated 2/27/19)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt*	NA
Drug Facts Continued	7 pt*	NA
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	NA
Barlines‡	> 0,5 pt rule	NA

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



Actual Size 100%

FDA00303-4

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/italic‡	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	6 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 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%

FDA00293-1



DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL ON 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.	6 pt.
Leading	≥0,5 pt.	4,5 pt.
Headlines	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



200%



Actual Size 100%

FDA00274-5

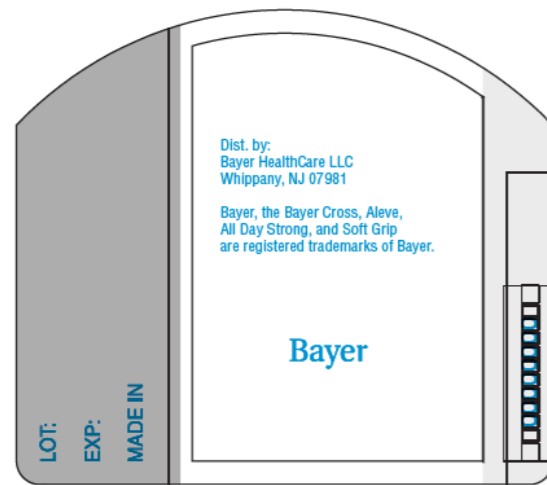


200%



Actual Size 100%

FDA00300-1

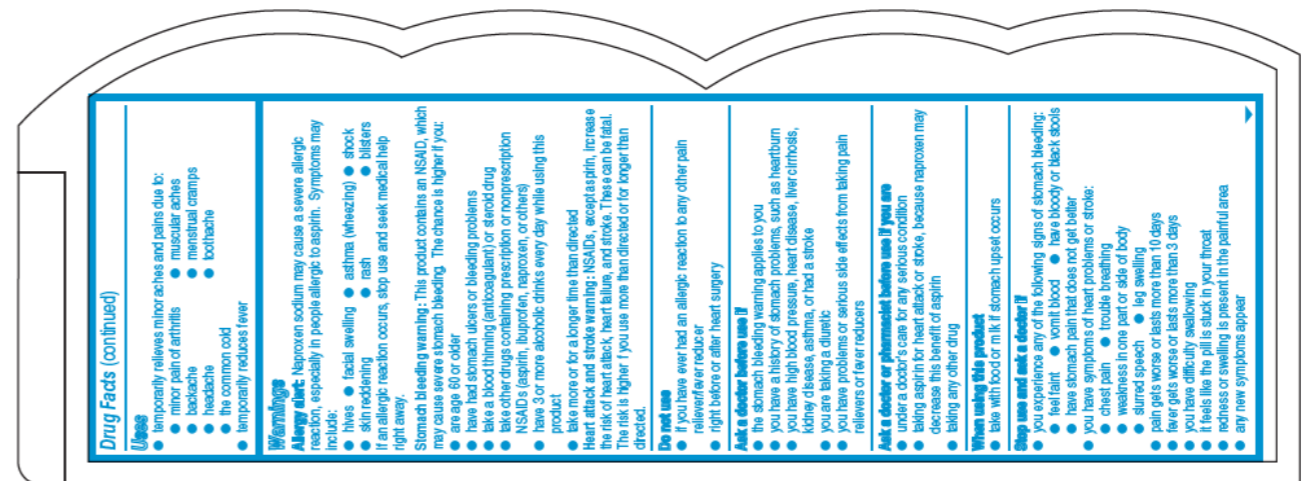
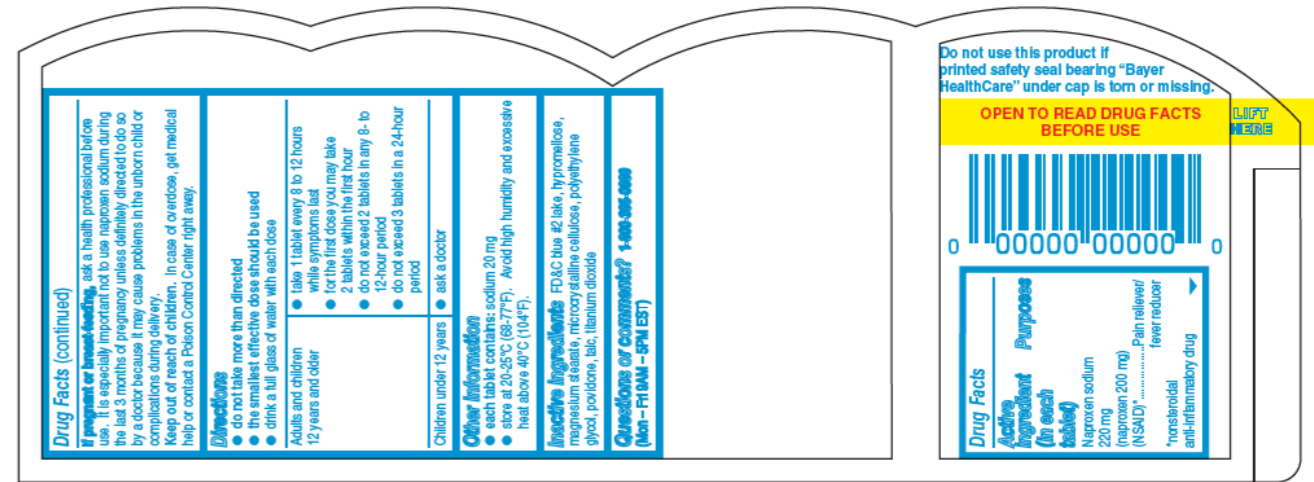


Actual Size 100%

FDA00170-1

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 Bar lines†	>0.5 pt.-rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

* Headings are to be at least 2x 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

FDA00289-3

DRUG FACTS INFO	UPDATED 5/18/19	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8 pt.	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.	8 pt.
Headings [†]	8 pt. Bold Italic [‡]	8 pt.	8 pt.
Subheadings	≥6 pt.	6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.	6 pt.
Bullets	5 pt.	1/2 pt.	1/2 pt.
Leading	≥0.5 pt.	6.5 pt.	6.5 pt.
Headlines	0.5 pt. rule	0.5 pt.	0.5 pt.
Box and Barlines [§]	>0.5 pt. rule	2.5 pt.	2.5 pt.
Characters Per Inch:	No more than 30	≤ 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 DFP.
[‡] FDA recommends 2.5 pt. rule.



Actual Size 100%

FDA00306-1

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.
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 types used in DFP
† FDA Recommends 2.5pt rule

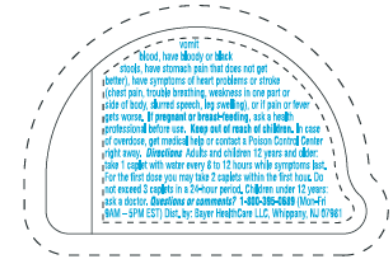
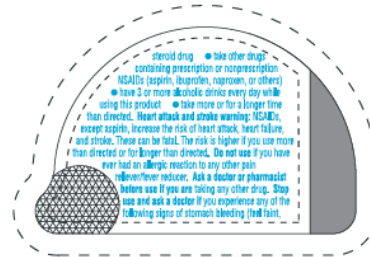
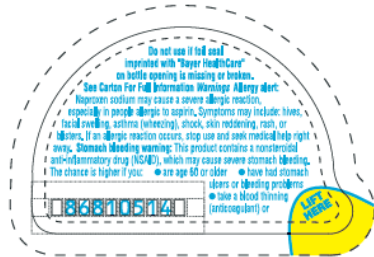


200%



Actual Size 100%

FDA00408-2



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 [†]	-
Subheadings	6 pt*	4,5 pt
Body Text	6 pt*	4,5 pt
Bullets	5 pt	8 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

Do not use if carton is open or if seal is impaired 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 during the last 3 months of 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?
+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.

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
 - muscular aches
 - backache
 - headache
 - menstrual cramps
 - toothache
- the common cold
- temporarily reduces fever

Uses

- 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
- facial swelling
- asthma (wheezing)
- shock
- 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 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

LOT & EXP CODE AREA

Actual Size 100%

FDA00281-4

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 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

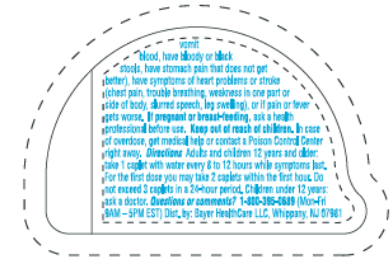


200%



Actual Size 100%

FDA00407-2



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*	-
Subheadings	6 pt*	4,5 pt
Body Text	6 pt*	4,5 pt
Bullets	5 pt	8 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



Actual Size 100%

FDA00304-3

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/italic [†]	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	6 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 28 [†]	≤ 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%

FDA00284-1



DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	-
Drug Facts Continued	8 pt	-
Headings†	8 pt-10pt <i>italic</i> ‡	-
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

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 during the last 3 months of 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?
1-800-395-0899 (Mon-Fri 9AM - 5PM EST)

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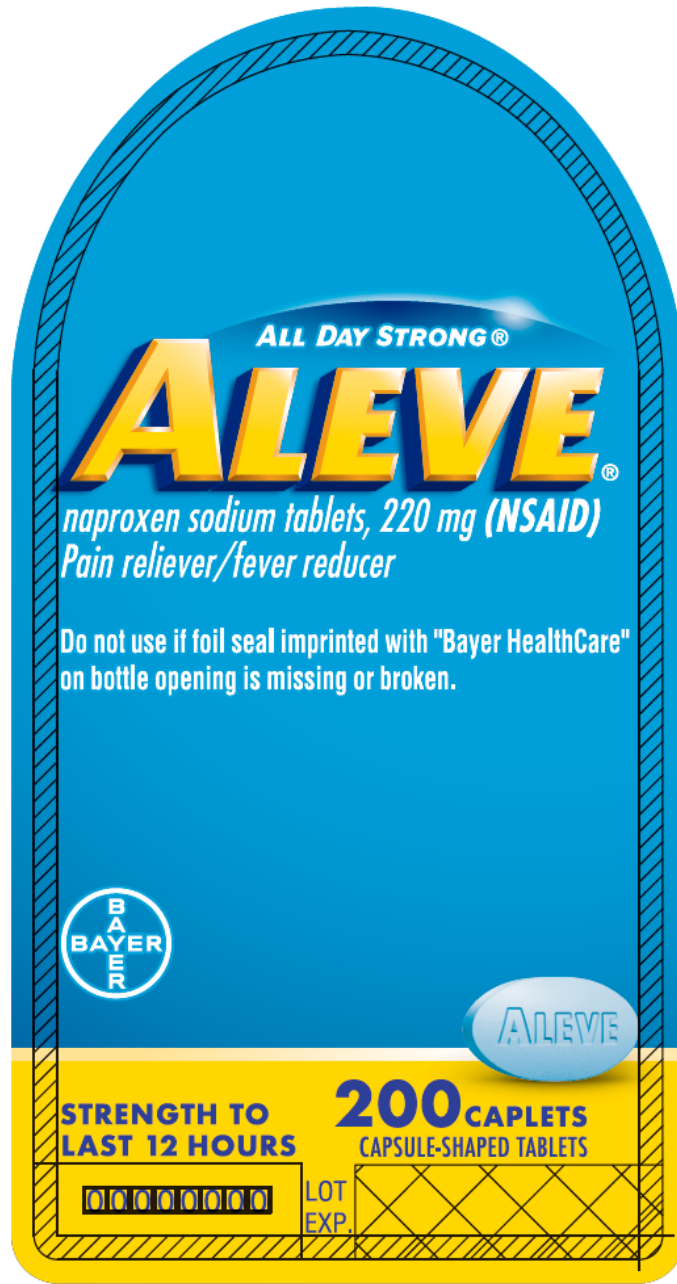
LOT & EXP CODE AREA

Actual Size 100%

FDA00282-3

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
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 6 pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DDP.
† FDA Recommends 2.5pt rule



200%



Actual Size 100%

FDA00409-3

See Carton for Full Information

Warning: 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, 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 thinner (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.

Head 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 disease, 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 like 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 go away), have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg pain), pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, you have difficulty swallowing, 1 look 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 during the last 3 months of 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. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). **Use of sun or tanning?** 1-800-318-4888 (Mon-Fri 9AM - 5PM EST)

Made in the USA

Mfg. by: Bayer HealthCare LLC
 Whippany, NJ 07981

Actual Size 100%

FDA00250-1

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.	8 pt.
Hair lines	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

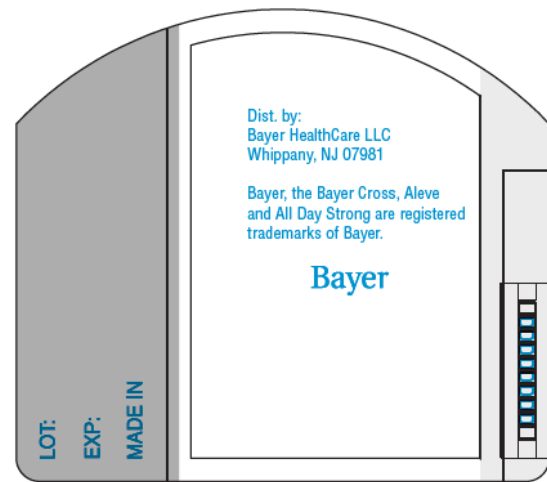


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Actual Size 100%

FDA00310-1

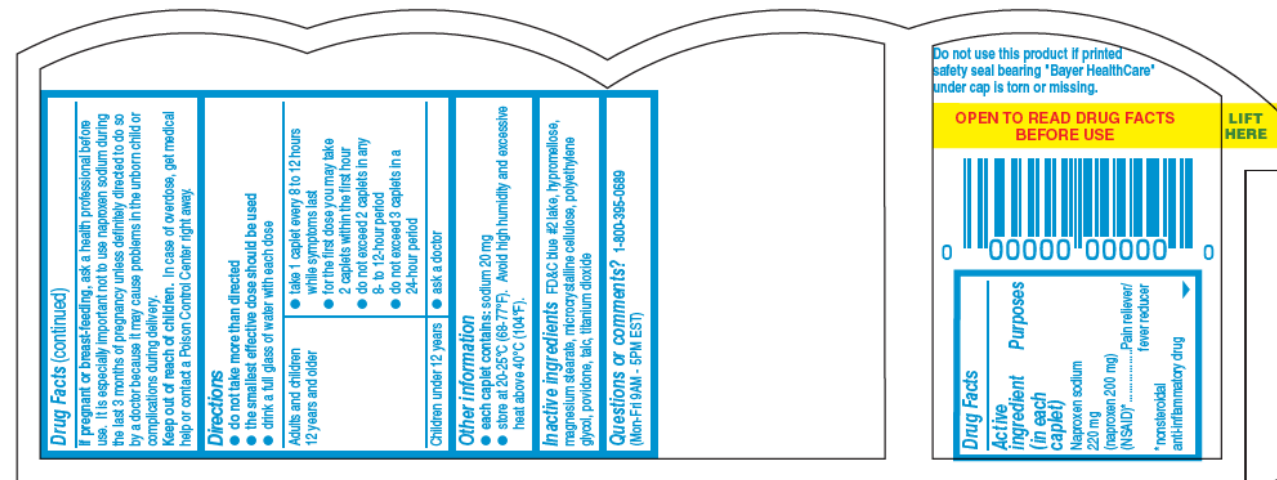
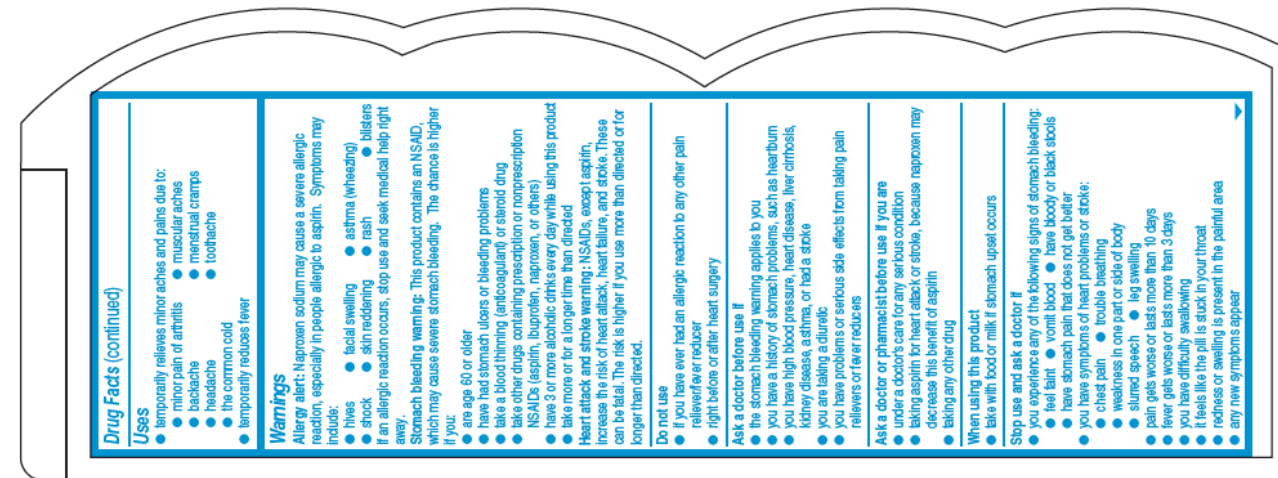


Actual Size 100%

FDA00183-1

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 38	≤38

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



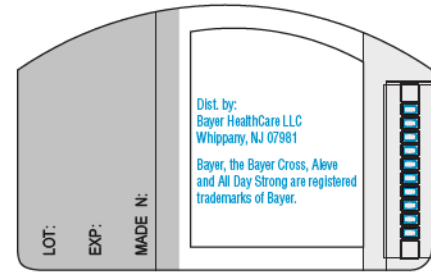


200%



Actual Size 100%

FDA00273-2



Actual Size 100%

FDA00215-7

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 Bar lines†	>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 DFP.
† FDA Recommends 2.5pt. rule.

Drug Facts (continued)

Uses

- temporarily relieves minor aches and pains due to:
 - muscle aches
 - muscular aches
 - nerve pain
 - headaches
 - toothache
 - the common cold
- temporarily reduces fever

Warnings

Always 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/itching, or blisters.

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

Bleeding warning: This product contains aspirin, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding
- take alcohol/drug
- take other drugs containing aspirin 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 †

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as: heartburn, high blood pressure, heart disease, liver disease, 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:
 - stomach pain
 - blood in vomit or stool
 - black stools
 - stomach pain that does not get better

Drug Facts (continued)

- you have symptoms of heart problems, such as:
 - chest pain
 - trouble breathing
 - swelling in the feet or side of the body
 - slurred speech
 - leg swelling
- your joints were or last more than 10 days
- your eyes were or last 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 genital area
- any new symptom in a year

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless 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 with 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: EPOC Blue 20, hydroxypropylcellulose, hydroxypropylmethylcellulose, polyethylene glycol, croscarmellose, talc, triethyl citrate

Questions or comments?
1-800-368-5600
(Non-FDA - PM EST)

Bayer

Drug Facts

Always 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/itching, or blisters.

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

Bleeding warning: This product contains aspirin, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding
- take alcohol/drug
- take other drugs containing aspirin 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 †

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as: heartburn, high blood pressure, heart disease, liver disease, 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:
 - stomach pain
 - blood in vomit or stool
 - black stools
 - stomach pain that does not get better



Actual Size 100%

FDA0317-1

CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt./bold/italic*	8 pt.
Subheadings	≥5 pt.	8 pt.
Body Text	≥5 pt.	8 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 title size used in DPP.
† FDA Recommends 2.5x rule.

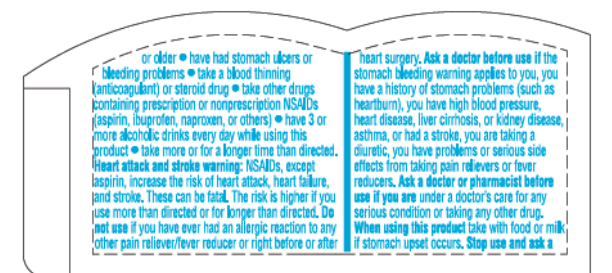
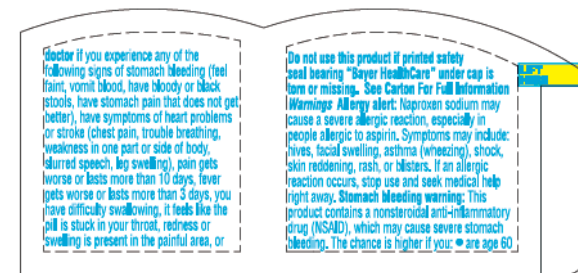
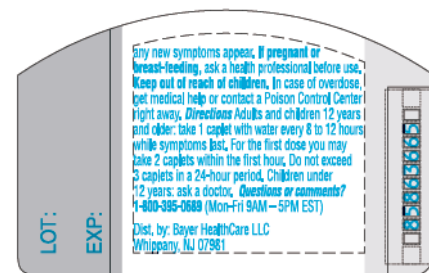


200%



Actual Size 100%

FDA00285-3



DRUG FACTS INFO <small>(updated 5/18/19)</small>		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	-
Drug Facts Continued	8 pt.	-
Headings*	8 pt-bold italic*	-
Subheadings	>6 pt.	6 pt.
Body Text	>6 pt.	6 pt.
Bullets	6 pt.	-
Leading	>0.5 pt.	6 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 sizes used in DFP
† FDA Recommends 2.5pt rule

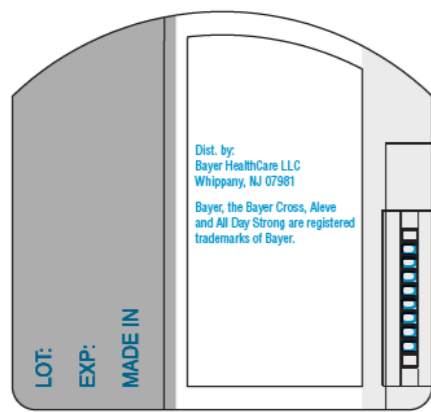


200%



Actual Size 100%

FDA00272-2



Actual Size 100%

FDA00174-1

DRUG FACTS INFO (updated 5/18/10)		
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 Barline†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 30	≤39

* Headings are to be at least 5 pts. larger than Body Text.
 ** Drug Facts Title to be larger than all other text used in DFP.
 † FDA Recommends 2.5pt. rule

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 when nursing the last 6 months of pregnancy unless advised by your health care provider. Naproxen 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**
- **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

Other Information

- each capsule 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: FDAC blue 42 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments? 1-800-858-0880 (NAP-PRO-ASK)

Bayer

Drug Facts

Active Ingredient (in each capsule): Naproxen sodium 200 mg (NSAID)[†]

Purpose: Pain reliever/fever reducer

†Nonsteroidal anti-inflammatory drug

Do not use this product if you are allergic to naproxen, aspirin, or other NSAIDs. See other directions for full details.

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Drug Facts (continued)

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - headache
 - menstrual cramps
 - 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)
- 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 aged 60 or older
- take aspirin or other drugs with bleeding problems
- take a blood thinner (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
- use 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 risks may be higher if you use naproxen for a long time. The longer you use naproxen, the higher the risk. The longer you use naproxen, the higher the risk. The longer you use naproxen, the higher the risk. The longer you use naproxen, the higher the risk.

Do not use

- if you have ever had an allergic reaction to any other NSAID
- if you have a history of stomach problems, such as heartburn
- if you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- if you are taking a diuretic
- if 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 of your body
 - slurred speech
 - leg swelling



Actual Size 100%

FDA00401-4

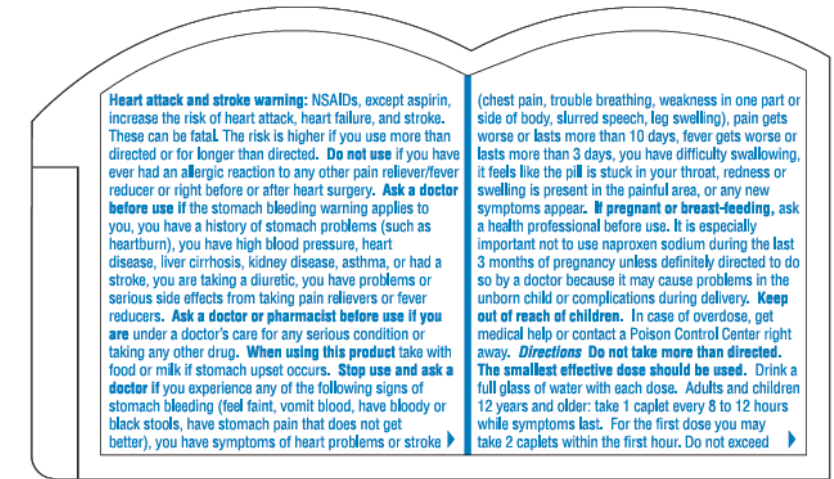
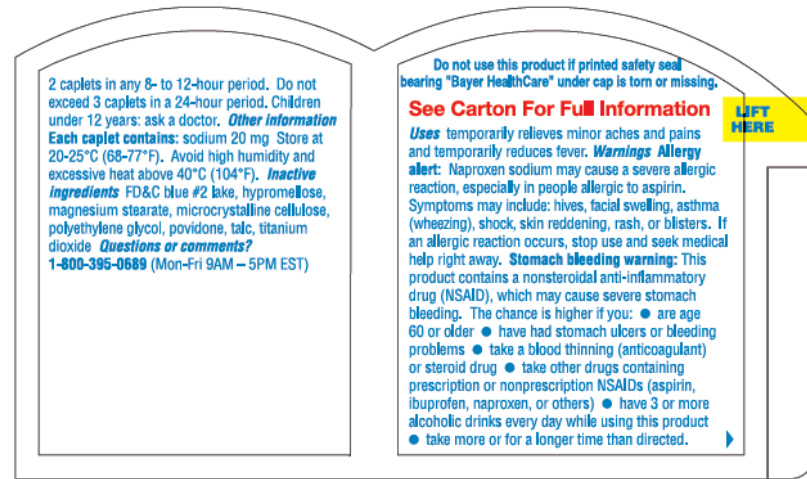
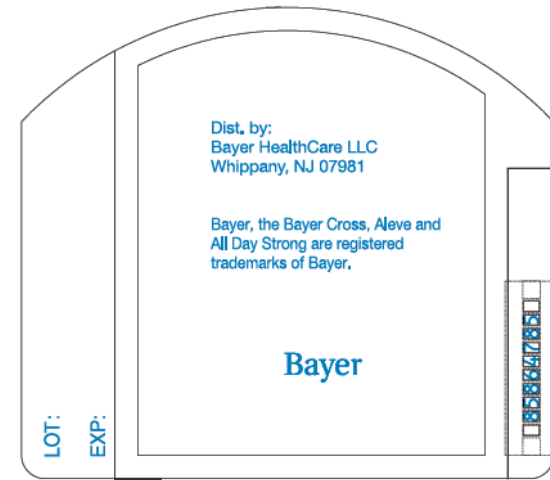
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Drug Facts Title	>8 pt **	8.1 pt
Drug Facts Content	8 pt	8 pt
Headings	5 pt bold caps*	5 pt
Subheadings	>5 pt	5 pt
Body Text	>5 pt	5 pt
Bullets	5 pt	12 pt
Linking	>0.5 pt	1 pt
Footnotes	0.5 pt rule	0.5 pt
Box and Barlines	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 30	< 30

* Headings are to be at least 30% larger than Body Text.
** Drug Facts Title to be larger than all other type size used in ODP if FDA Recommendation is 24 pt min.



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
Loading	≥0.5 pt	7 pt
Headlines	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 2 pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP
^{††} FDA Recommends 2,5pt rule

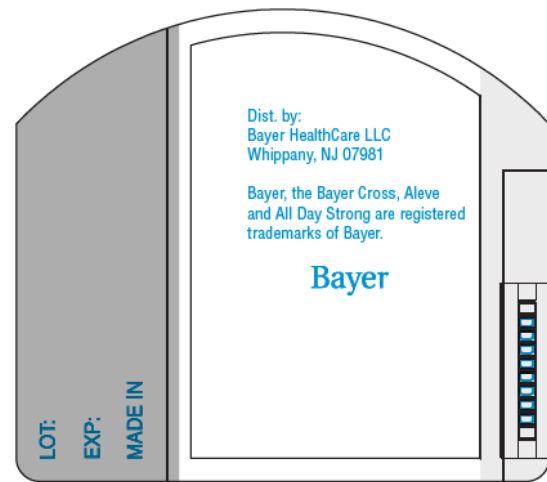


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Actual Size 100%

FDA00307-3

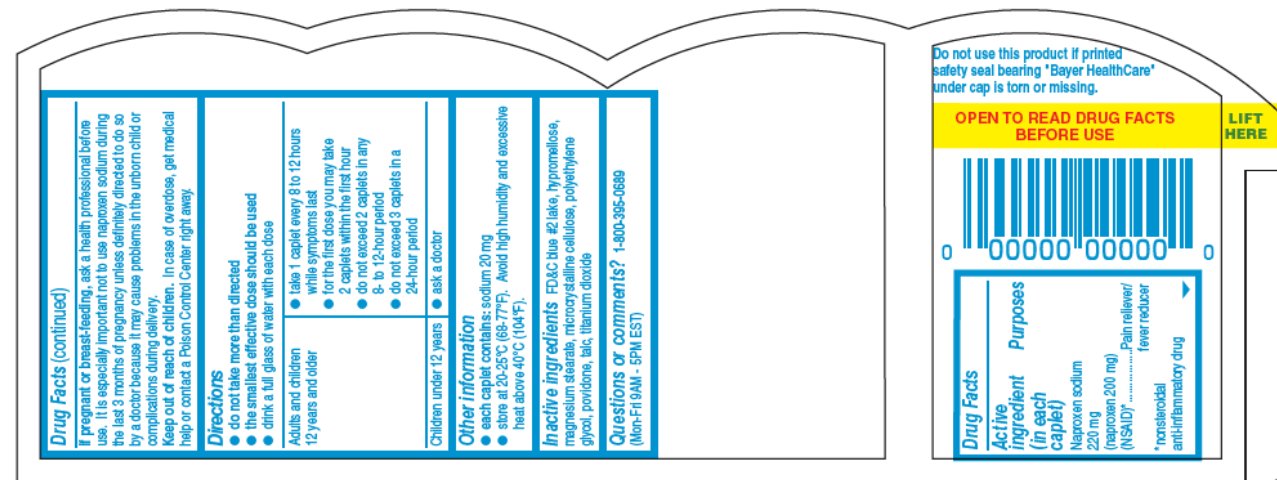
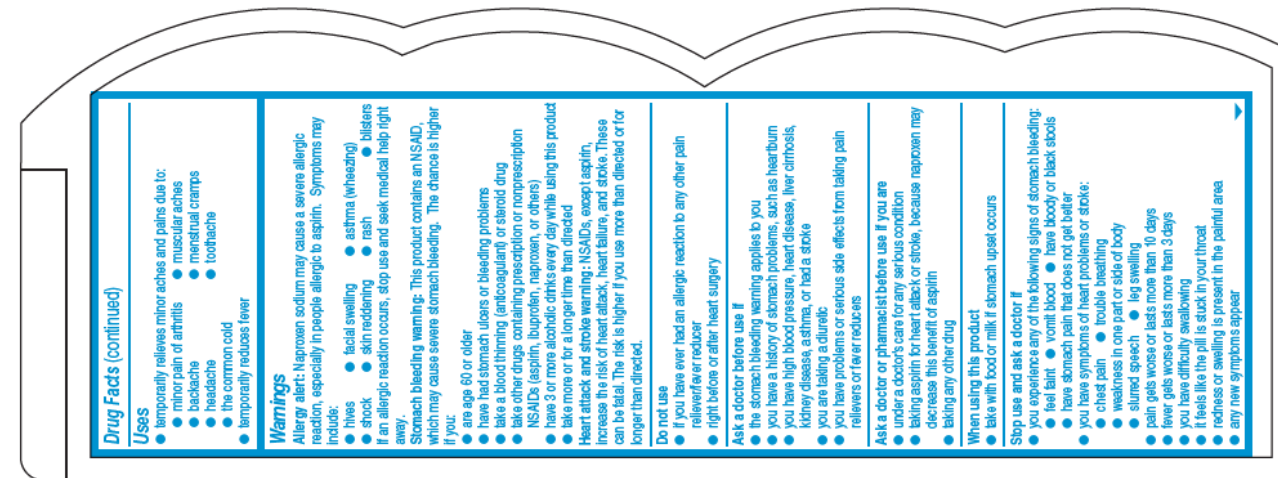


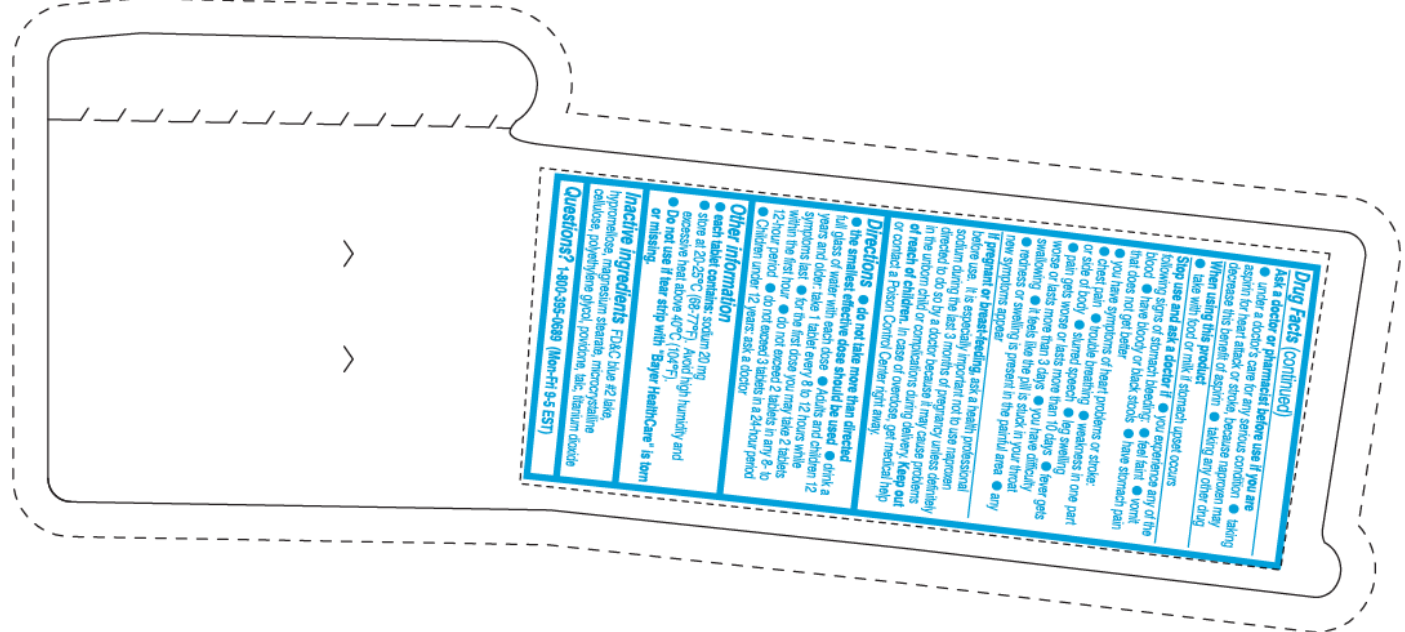
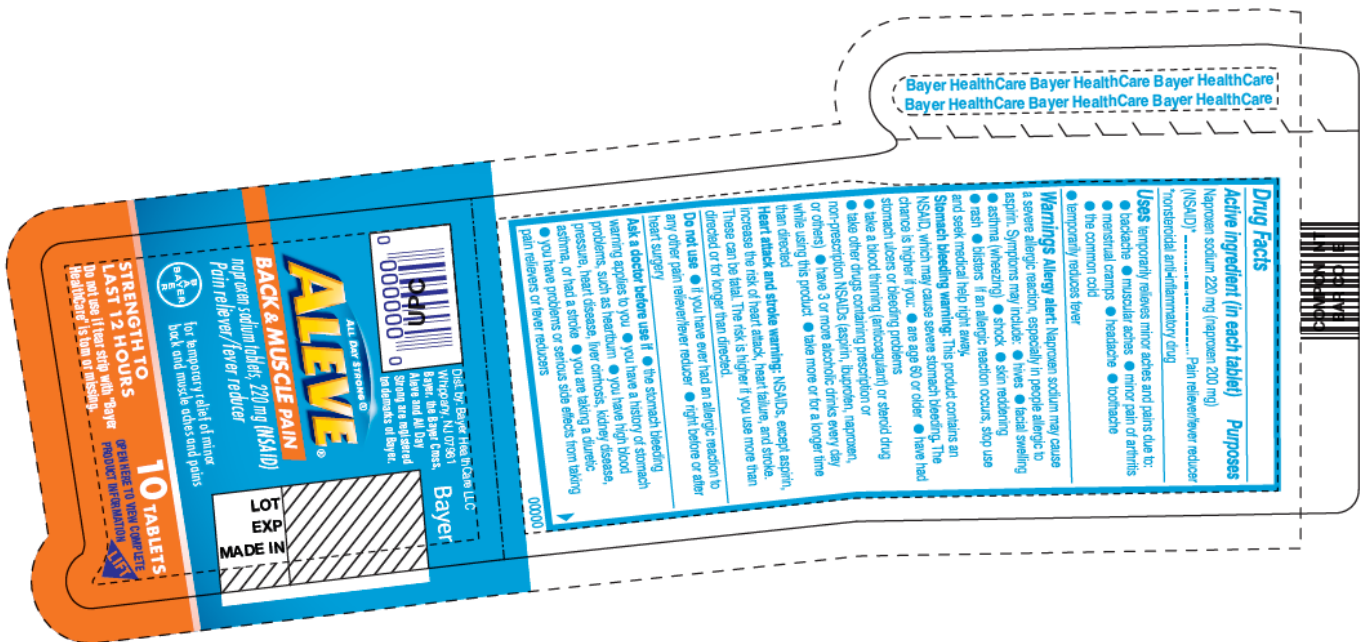
Actual Size 100%

FDA00183-1

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 38	≤38

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





Actual Size 100%

FDA00298-3

DRUG FACTS INFO (updated 5/18/19)		
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.	6-6.5 pt.
Hairlines	0.5 pt. rule	.5 pt.
Box and Barlineart	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 38	≤ 38

* Headings are to be at least 2pts larger than Body Text.
** Drug Facts title to be larger than a 1 other type size used in ODP
† FDA recommends 2.5pt rule

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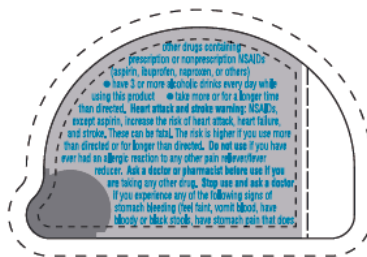


Actual Size 100%

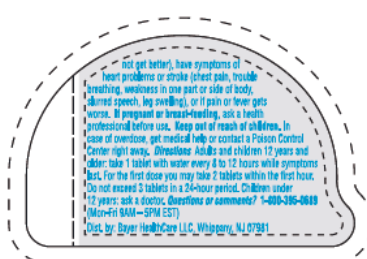
FDA00278-4



Panel 1 Top



Panel 2 Inside



Panel 3 Base

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
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		



Actual Size 100%

FDA00283-4

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.
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 DPP
† FDA Recommends 2.5pt. rule



200%

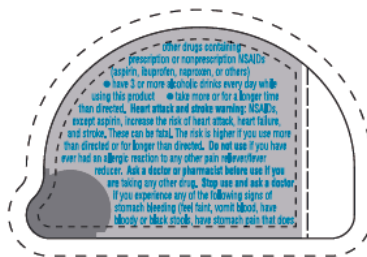


Actual Size 100%

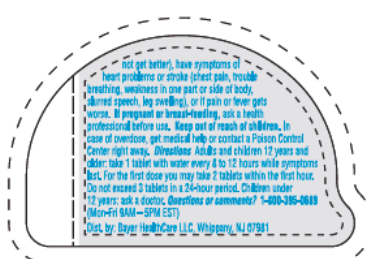
FDA00405-2



Panel 1 Top



Panel 2 Inside



Panel 3 Base

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
Hairlines	0,5 pt rule	-
Barlines†	> 0,5 pt rule	-
<small> Characters per inch rule is not applicable to ICL. *ICL minimum font size is 4,5 pt. † FDA recommends size 2,5 pt type. </small>		



Actual Size 100%

FDA00302-2

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 italic‡	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	6 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 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%

FDA00271-1



100%

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	-
Drug Facts Continued	8 pt.	-
Headings*	8 pt-bold italic*	-
Subheadings	≥6 pt.	4.5 pt.
Body Text	≥6 pt.	4.5 pt.
Bullets	5 pt.	8 pt.
Leading	≥0.5 pt.	0 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 ODP
 † FDA recommends 2.5pt rule



Actual Size 100%

FDA00309-3

DRUG FACTS INFO updated 5/19/19

CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	9 pt
Drug Facts Content	8 pt	8 pt
Headings*	6 pt bold caps*	6 pt
Subheadings	>6 pt	6 pt
Body Text	>6 pt	6 pt
Bullets	5 pt	12 pt
Lineing	>0.5 pt	0.5 pt
Footlines	0.5 pt rule	0.5 pt
Bar and Barlines†	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 30	<30

* Headings are to be at least 30% larger than Body Text.
** Drug Facts title to be larger than all other type size used in ODP if FDA Recommendation is 8 pt rule.

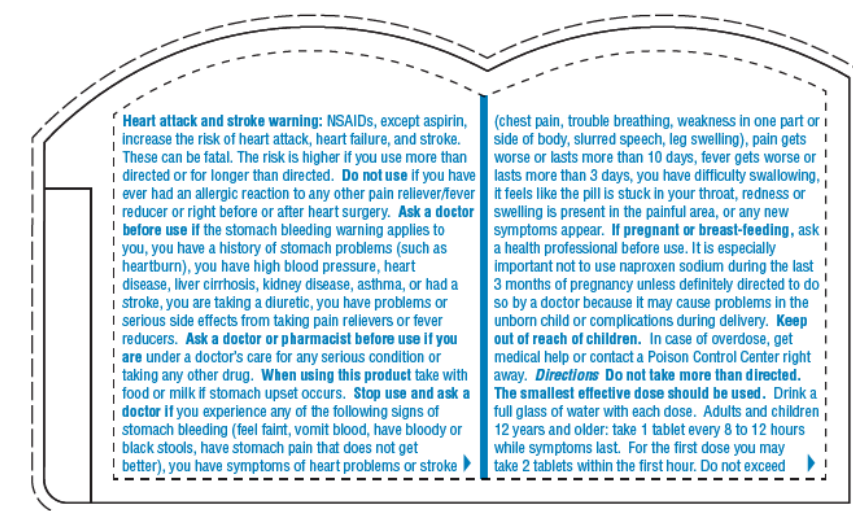
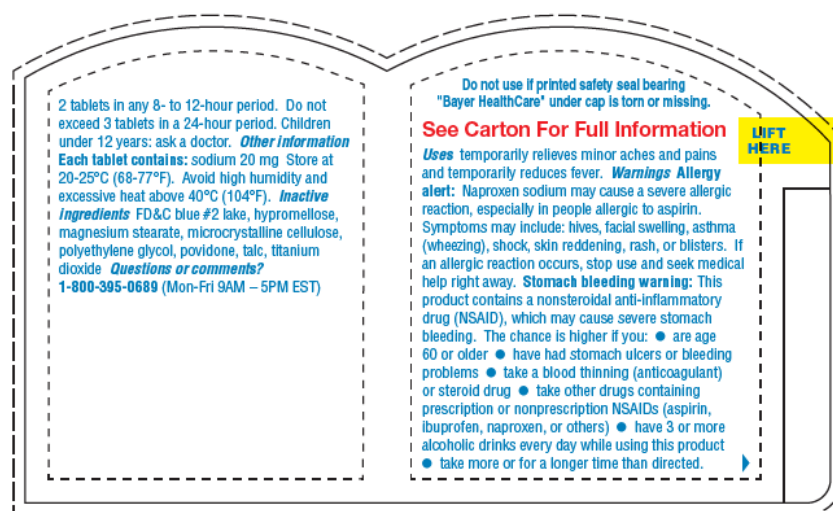
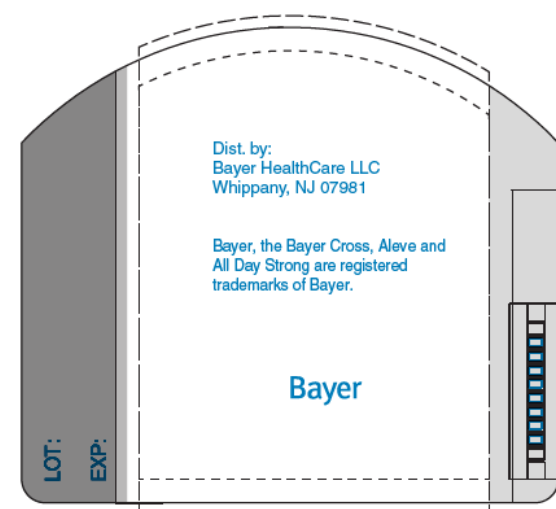


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Actual Size 100%

FDA00277-3



Actual Size 100%

FDA00246-2

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*	6 pt
Subheadings	6 pt*	6 pt
Body Text	6 pt*	6 pt
Bullets	5 pt	12 pt
Horizontal	0.5 pt rule	-
Vertical	> 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



Actual Size 100%

FDA00400-2

CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	9 pt
Drug Facts Content	8 pt	8 pt
Headings*	6 pt bold call*	6 pt
Subheadings	>8 pt	6 pt
Body Text	>8 pt	6 pt
Bullets	6 pt	12 pt
Lineing	>0.5 pt	0.5 pt
Footlines	0.5 pt rule	0.5 pt
Bar and Barlines†	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 30	<30

* Headings are to be at least 30% larger than Body Text.
** Drug Facts title to be larger than all other type size used in ODP.
† FDA Recommendation: 5-6pt rule.

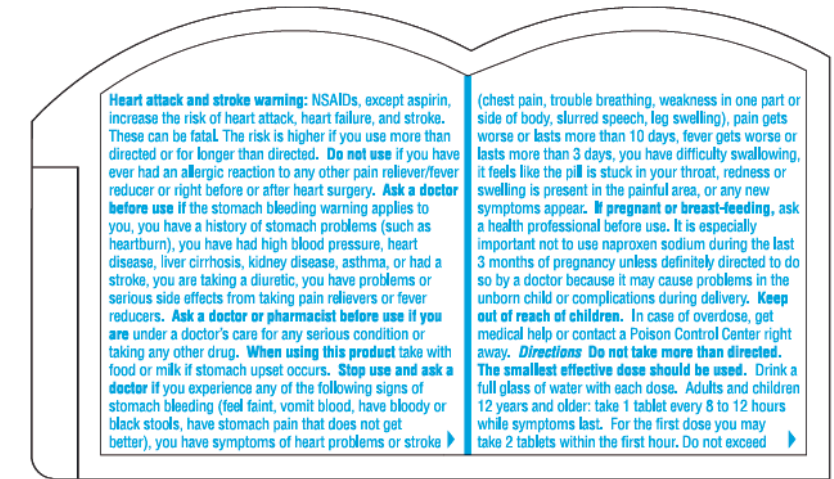
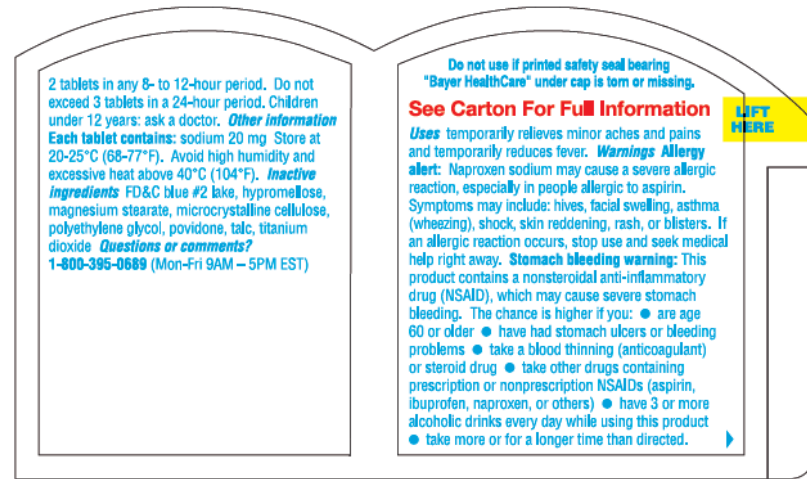
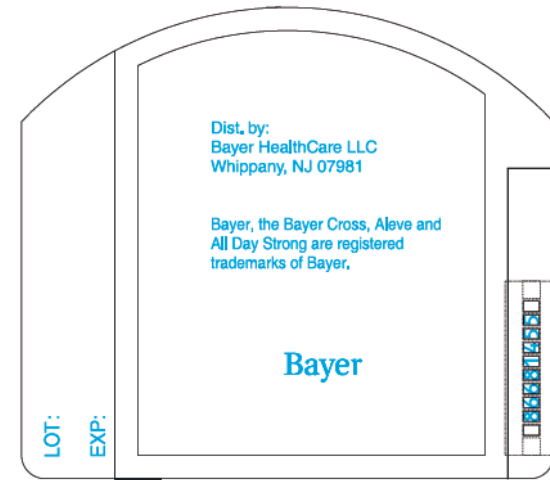


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Actual Size 100%

FDA00299-1



DRUG FACTS INFO: (Modified Format - updated 5/18/19)		
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	5 pt	12 pt
Leading	≥0 pt	1 pt
Headlines	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 Barline may be omitted and color contrast used to highlight Drug Facts info.



Actual Size 100%

FDA00324-3

DRUG FACTS IN PD (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt.**	8 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings†	8 pt./bold/italic*	8 pt.
Subheadings	≥5 pt.	8 pt.
Body Text	≥5 pt.	8 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 30	≤ 30

* Headings are to be at least 2px larger than Body Text.
** Drug Facts Title to be larger than all other text used in DPP.
† FDA Recommends 2.5px rule.

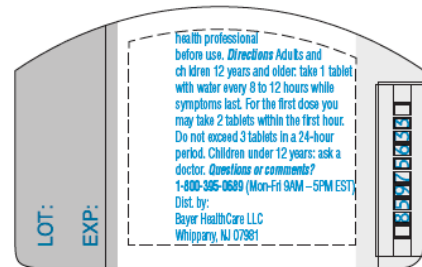


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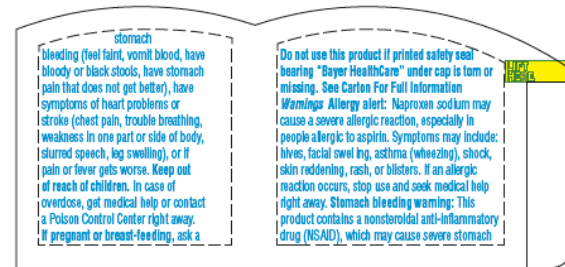


Actual Size 100%

FDA00275-5

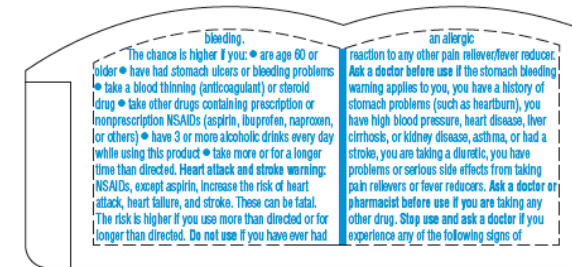


Health professional
 before use. *Directions* Adults and
 children 12 years and older: take 1 tablet
 with water every 8 to 12 hours while
 symptoms last. For the first dose you
 may take 2 tablets within the first hour.
 Do not exceed 3 tablets in a 24-hour
 period. Children under 12 years: ask a
 doctor. *Questions or comments?*
 1-800-395-0689 (Mon-Fri 9AM-5PM EST)
 Dist. by:
 Bayer HealthCare LLC
 Whippany, NJ 07981



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. Keep out
 of reach of children. In case of
 overdose, get medical help or contact
 a Poison Control Center right away.
 If pregnant or breast-feeding, ask a
 health professional before use. *Directions* Adults and
 children 12 years and older: take 1 tablet
 with water every 8 to 12 hours while
 symptoms last. For the first dose you
 may take 2 tablets within the first hour.
 Do not exceed 3 tablets in a 24-hour
 period. Children under 12 years: ask a
 doctor. *Questions or comments?*
 1-800-395-0689 (Mon-Fri 9AM-5PM EST)
 Dist. by:
 Bayer HealthCare LLC
 Whippany, NJ 07981

Do not use this product if printed safety seal
 bearing "Bayer HealthCare" under cap is torn or
 missing. 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.
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 taking any
 other drug. **Stop use and ask a doctor** if you
 experience any of the following signs of

DRUG FACTS INFO (updated 5/18/18)		
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	9 pt
Leading	≥0.5 pt	.5 pt
Headlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	< 39

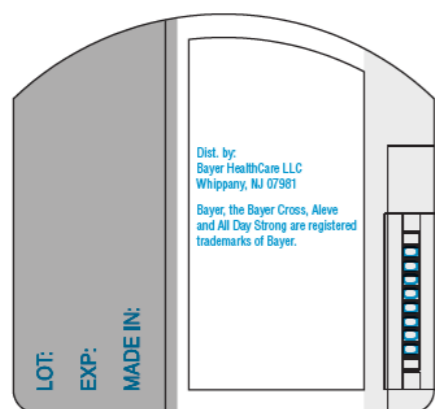
* Headings are to be at least 2pts larger than Body Text.
 ** Drug Facts Title to be larger than all other type size used in ODP
 † FDA recommends 2.5pt rule

200%



Actual Size 100%

FDA00288-3



Actual Size 100%

FDA00179-2

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.	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

Drug Facts (continued)

- pain reliever or fever reducer for 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 during the last 2 months of pregnancy unless advised by your 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

- **Aspirin should never be chewed.**
- **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 excursions that exceed 40°C (104°F).

Inactive Ingredients: DAC yellow #10 aluminum lake, edible doctum, edible ink, FD&C blue #1, FD&C yellow #6 aluminum lake, gelatin, glycerin, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polydioxane, stearic acid, talc, titanium dioxide

Questions or comments? 1-800-486-4800 (Aspirin-FI 9AM-4PM EST)

Bayer

Drug Facts

Action Indicated for each tablet Purpose

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

Do not chew tablets.
 Do not take more than 3 tablets in a 24-hour period.

LOT

EXP

MADE IN

Drug Facts (continued)

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - backache
 - menstrual cramps
 - 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)
- skin redness/itching
- rash
- shock
- dizziness
- fainting
- trouble breathing
- swelling in the face, lips, tongue, or throat

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 risk is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take more alcohol 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 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 this may increase the risk of bleeding
- 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 upset:
 - heartburn
 - indigestion
 - loss of appetite
 - stomach pain
 - vomiting
 - blood in stool
 - black stools
 - dark stools
 - stools that look like coffee grounds
- 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
 - big swelling