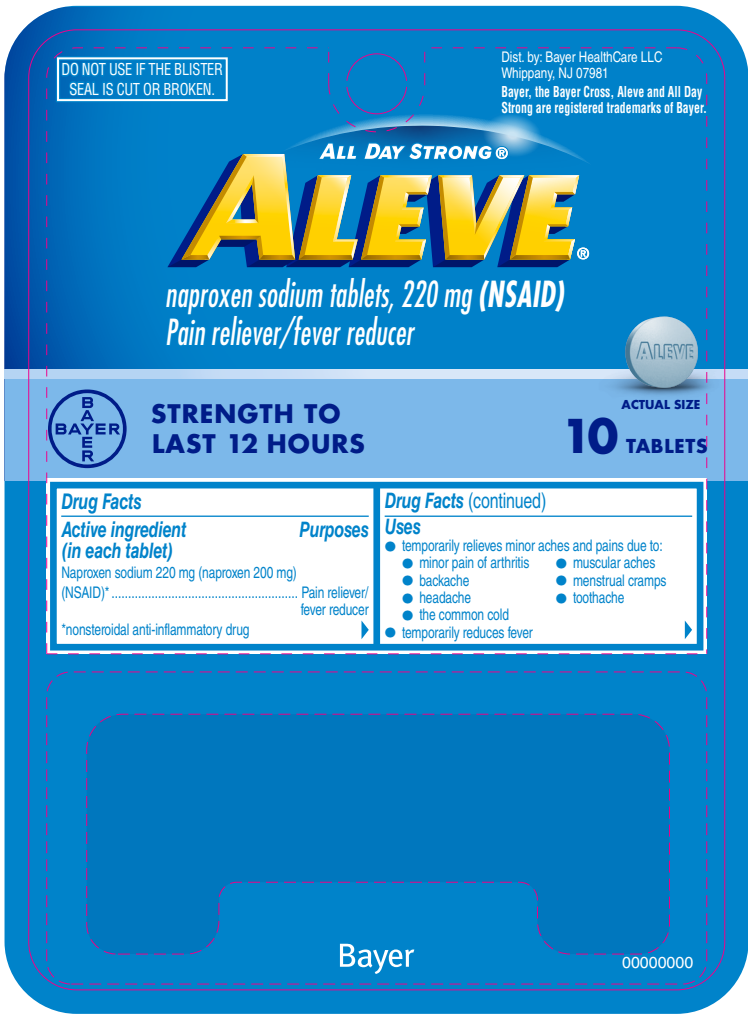
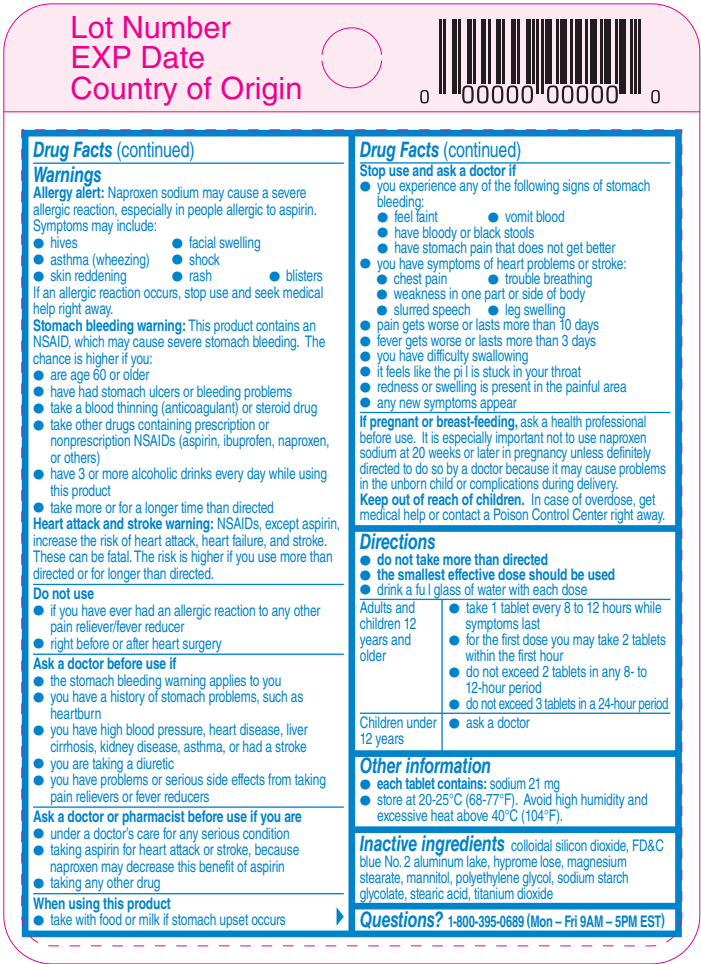




FRONT

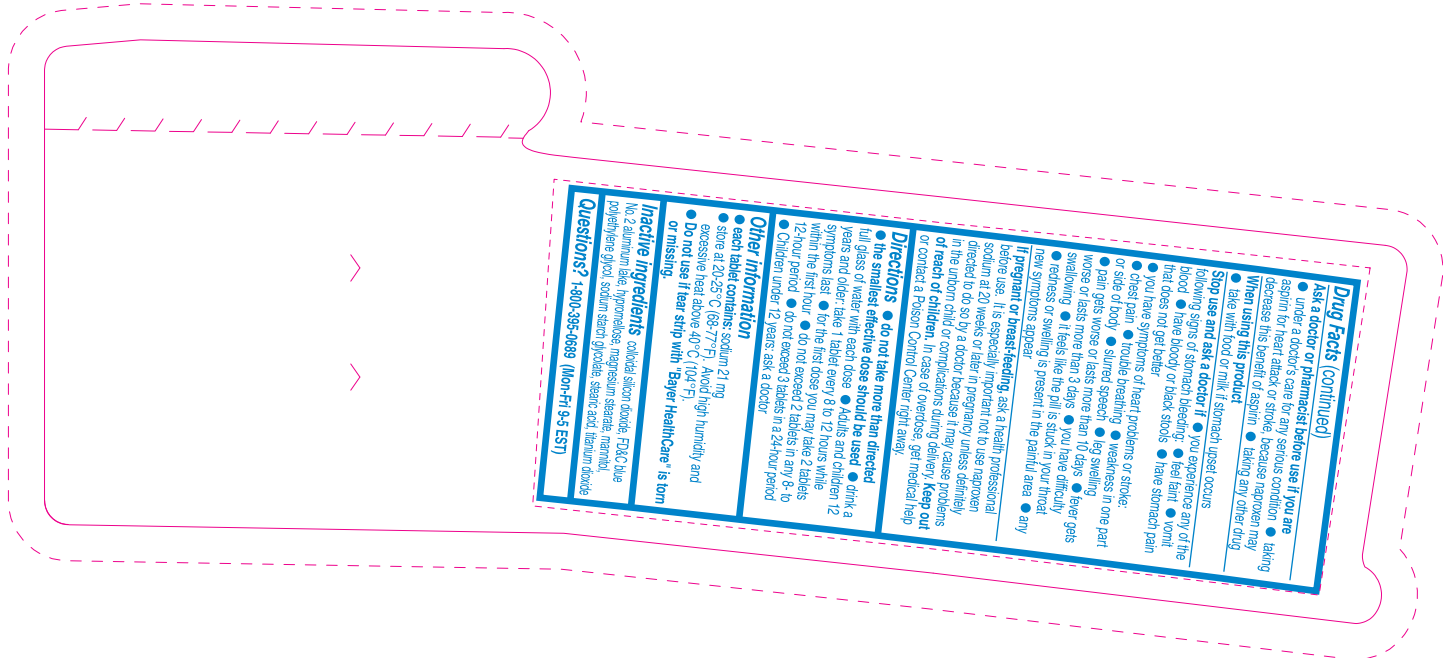


BACK

Actual Size 100%

FDA43359-2

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
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		



Actual Size 100%

FDA40367-3

DRUG FACTS INFO: (Modified Format – updated 5/8/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	8.1 pt
Drug Facts Continued	7 pt	8 pt
Headings ^a	7 pt- <i>bold italic</i> ^b	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
Headlines	≥0.5 pt rule	5 pt
Box and Barlines ^c	>0.5 pt rule	2.5 pt
Characters Per Inch:	More than 39	≤ 39

^a Headings are to be at least 2x larger than Body Text

^b Drug Facts Title to be larger than all other type size used in DFP

^c Box Barline may be omitted and color contrast used to highlight Drug Facts Info



Actual Size 100%

FDA40323-2

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	1/2 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 3pts larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DPP
[†] FDA Recommends 2 Spt rule



Actual Size 100%

FDA45258-1

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 pt - 0.5 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barline†	>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		



Actual Size 100%

FDA47724-1

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 ¹	8 pt-bold italic ⁴	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 ¹	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

¹ Headings are to be at least 2 pts larger than Body Text.
⁴ Drug Facts Title to be larger than all other type size used in DPP
¹ FDA Recommends 2.5pt rule



Actual Size 100%

FDA47729-1

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 ¹	8 pt-bold italic ⁴	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 ¹	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

¹ Headings are to be at least 2 pts larger than Body Text.
⁴ Drug Facts Title to be larger than all other type size used in DPP
¹ FDA recommends 2.5pt rule.

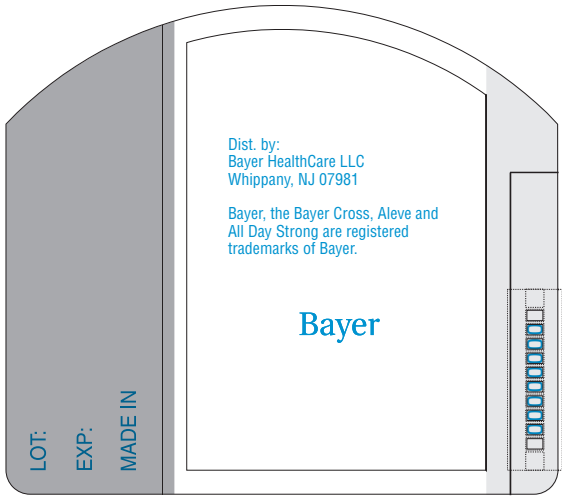


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Actual Size 100%

FDA00274-5



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 specifically directed to do so by a health professional. 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
- do not take with other NSAIDs unless directed to be used
- do not take with alcohol
- 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
- do not take more than 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 21 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive Ingredients: coloidal silicon dioxide, FD&C blue No. 2 aluminum lake, hypromellose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or Comments? 1-800-365-0080 (Mon – Fri 9AM – 5PM EST)

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 00000 00000 0

Drug Facts

Active Ingredient (In each tablet)

Naproxen sodium 220 mg (Naproxen 200 mg) (NSAID).....

Purposes

Pain reliever/fever reducer

*Nonsteroidal anti-inflammatory drug

Drug Facts (continued)

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - headache
 - menstrual cramps
- 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

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

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, including aspirin, or use alcohol while taking this product
- 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 take if you:

- have ever had an allergic reaction to any other pain reliever/fever reducer
- are taking aspirin or other drugs for heart problems

Ask a doctor before use if

- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver disease, kidney disease, asthma, or had a stroke
- 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:
 - black, tarry stools
 - blood in stool or dark 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 dizziness or lightheadedness 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

Actual Size 100%

DRUG FACTS INFO (Updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{1,2}	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ¹	8 pt.-bold italic ²	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 Barline(s)	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 38	≤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

FDA-40353-1



Actual Size 100%

FDA45166-2

DRUG FACTS INFO Updated: 5/18/18		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ¹⁴	9 pt
Drug Facts Continued	8 pt	8 pt
Headings ¹⁴	8 pt-bold-italic ¹⁴	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 Borderline	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 30	<30

¹⁴ Headings are to be at least 24pt larger than Body Text.
¹⁵ Drug Facts Title to be larger than all other type size used in DPP.
¹⁶ FDA recommends 2.5pt rule.

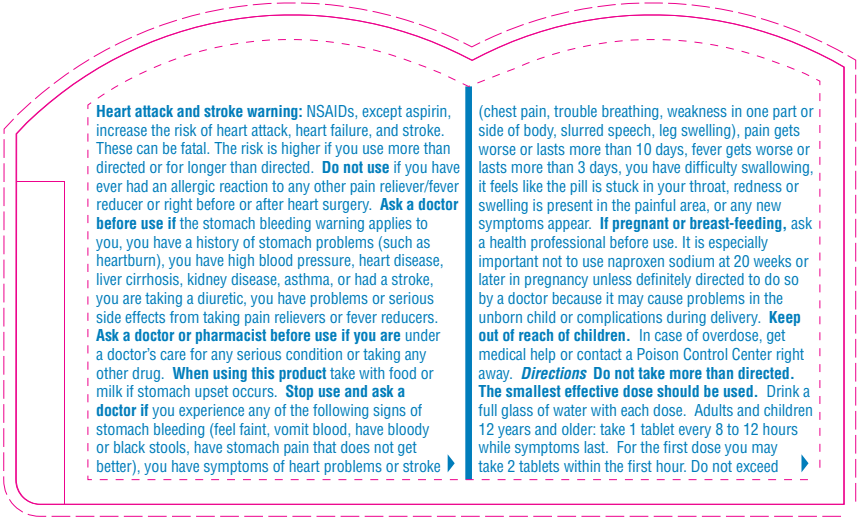
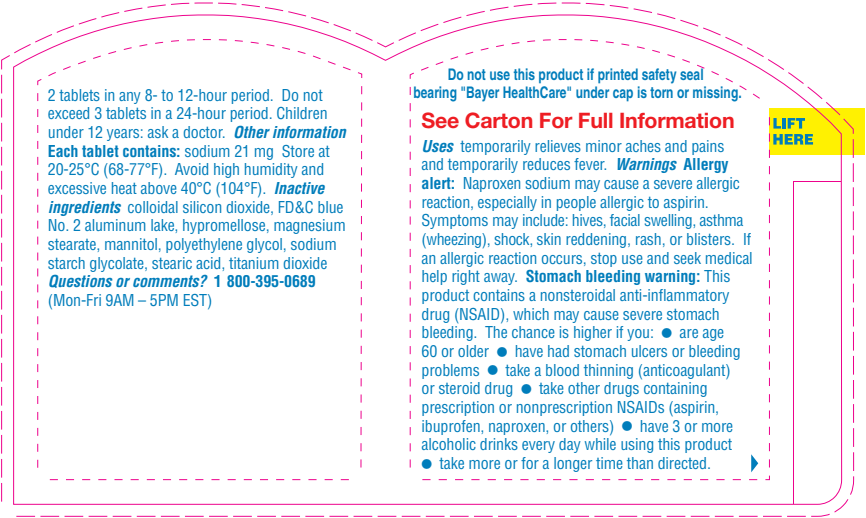
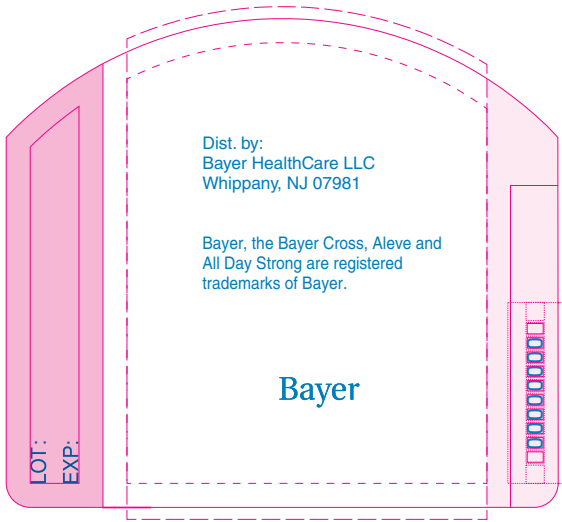


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Actual Size 100%

FDA00386-2



Actual Size 100%

FDA45152-5

DRUG FACTS INFO: (Modified Format – updated 5/18/18)		
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		

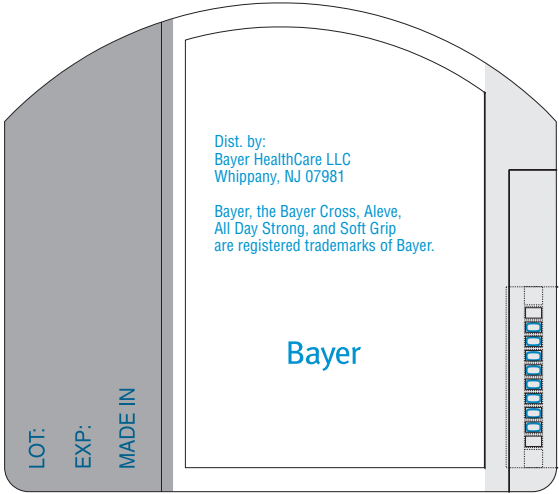


200%



Actual Size 100%

FDA00300-1



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

Inactive Ingredients: coloidal silicon dioxide, FD&C blue No. 2, aluminum lake, hypromellose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments? 1-800-368-6000 (Mon-Fri 9AM-5PM EST)

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 000000 000000 0

Drug Facts

Active Ingredient (in each tablet)

Naproxen sodium
220 mg
(naproxen 200 mg)

"NSAID".....Pain reliever/
fever reducer

"nonsteroidal
anti-inflammatory drug"

Drug Facts (continued)

Uses

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

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 ● 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 aspirin, including low-dose aspirin, or other 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 aspirin, blood thinners, or other pain relievers or fever reducers
- 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- taking any other drug

When taking 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
- nausea or vomiting is present in the painful area
- any new symptoms appear

Actual Size 100%

FDA-40363-3

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.	0.5 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

Reference ID: 5152904



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

Actual Size 100%

FDA45097-0

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 ¹	8 pt-bold <i>italic</i> ²	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 ³	>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.



Actual Size 100%

FDA40011-3

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 - 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 3pts larger than Body Text.
** Drug Facts Title to be larger than all other type size used in DPP
† FDA Recommends 2.5pt rule

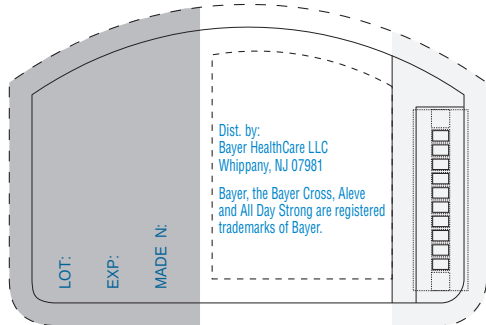


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Actual Size 100%

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 take 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
- shock
- stomach bleeding

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

Some health 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 warnings: 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 you use if you

- 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 you use if you

- 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:
 - feet faint
 - stomach pain that does not get better

	Drug Facts (continued)
	Warnings
	Important information:
	Take with food:
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Actual Size 100%

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 <i>italic</i> *	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.
Headlines	0.5 pt rule	0.5 pt.
Box and Barlines†	>0.5 pt rule	2.5 pt.
Characters Per Inch:	more than 39	<39

* Headings are to be at least 20% longer 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%

FDA45178-1

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 pt - 0.5 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barline†	>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		



Actual Size 100%

FDA45169-3

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{1,2}	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings ³	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 Barlineart ⁴	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 20	≤ 20

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 DFP
³ FDA Recommends 2.5pt. rule



Actual Size 100%

FDA45183-3

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ^{1,4}	9 pt
Drug Facts Continued	8 pt	8 pt
Headings ¹	8 pt-bold italic ¹	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 ¹	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

¹ Headings are to be at least 2 pts larger than Body Text.
⁴ Drug Facts Title to be larger than all other type size used in DPP
¹ FDA Recommends 2.5pt rule

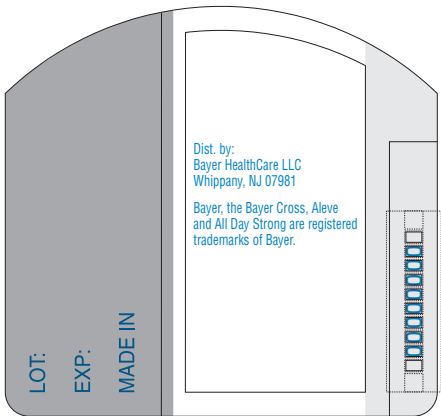


200%



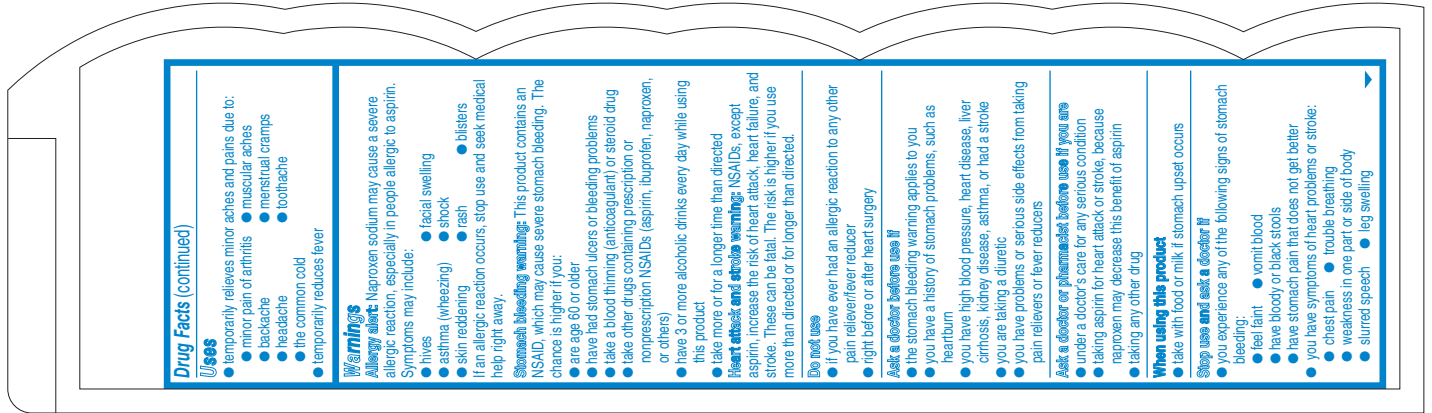
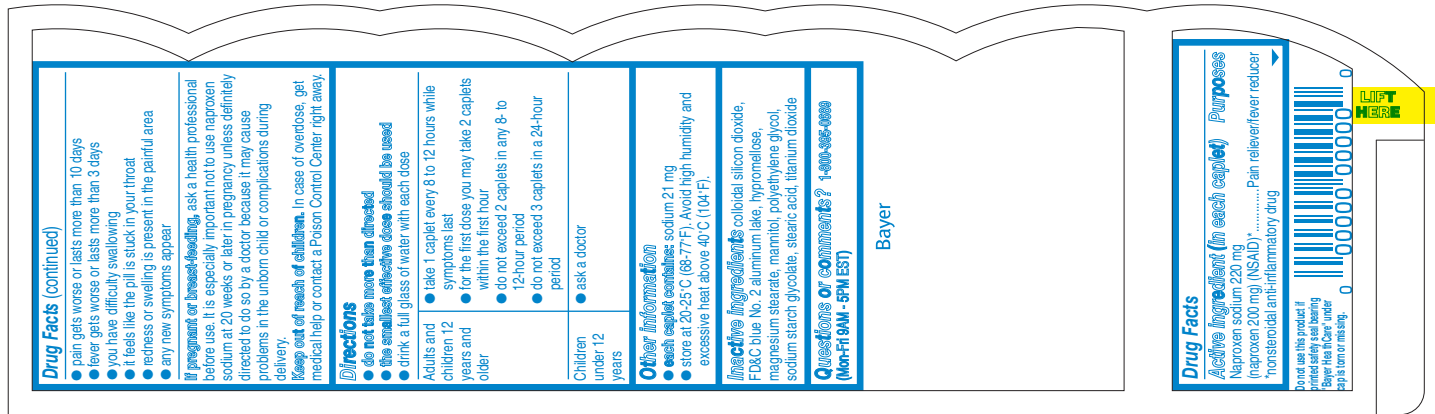
Actual Size 100%

FDA00272-2



Reference ID: 5152904

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For current labeling information, please visit <https://www.fda.gov/drugsatfda>**



Actual Size 100%

FDA43366-1

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	>8 pt	6 pt
Body Text	>8 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 Line	No more than 39	<39

* Headings are to be at least 2x larger than Body Text.
† Box and Barline are to be larger than all other type size used in DFP
† FDA Recommends 2.5 pt. rule

* 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 3 font rule



Actual Size 100%

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ^{1,4}	9 pt
Drug Facts Continued	8 pt	8 pt
Headings ¹	8 pt-bold italic ¹	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 ¹	≥0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

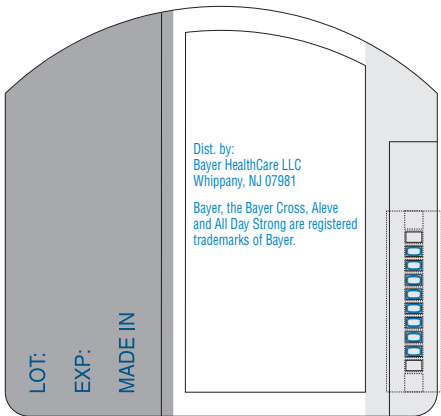
¹ Headings are to be at least 2 pts larger than Body Text.
⁴ Drug Facts Title to be larger than all other type size used in ODP
¹ FDA recommends 2.5pt rule.

200%



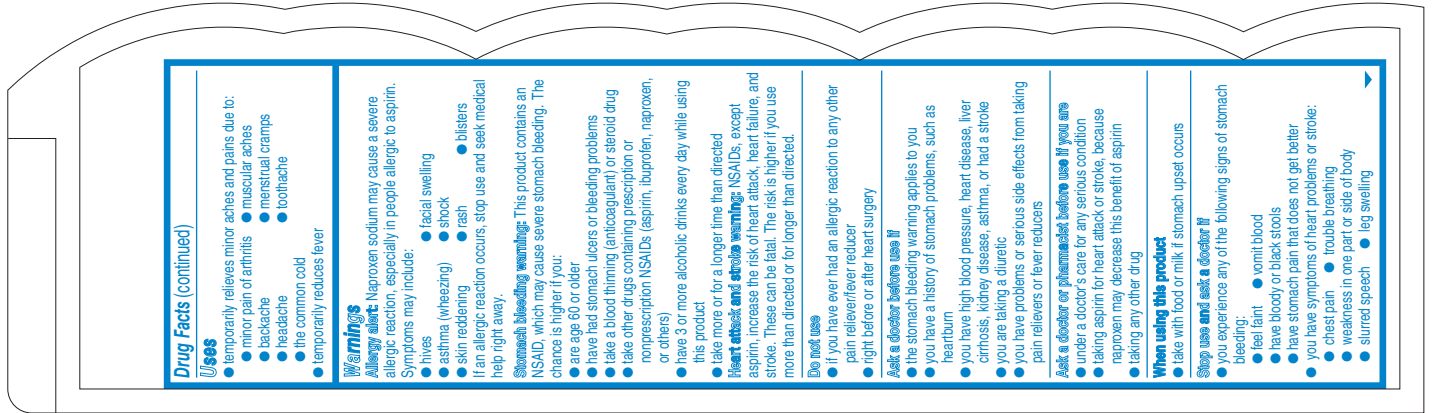
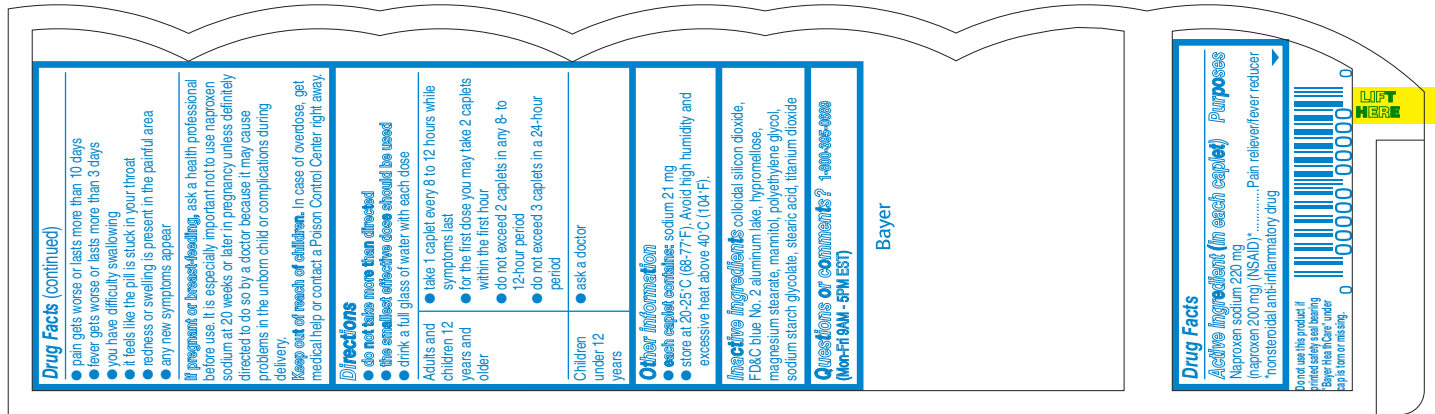
Actual Size 100%

FDA00373-2



Reference ID: 5152904

**This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfda>**



Actual Size 100%

FDA43366-1

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	>8 pt	6 pt
Body Text	>8 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 Line	No more than 39	<39

* Headings are to be at least 2x larger than Body Text.
† Box and Barline are to be larger than all other type size used in DFP
† FDA Recommends 2.5 pt. rule

* 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 3 font rule



Actual Size 100%

FDA45181-2

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ^{1,2}	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings ¹	8 pt-bold <i>italic</i> ²	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 ²	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 38	≥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 DFP
³ FDA recommends 2.5pt rule

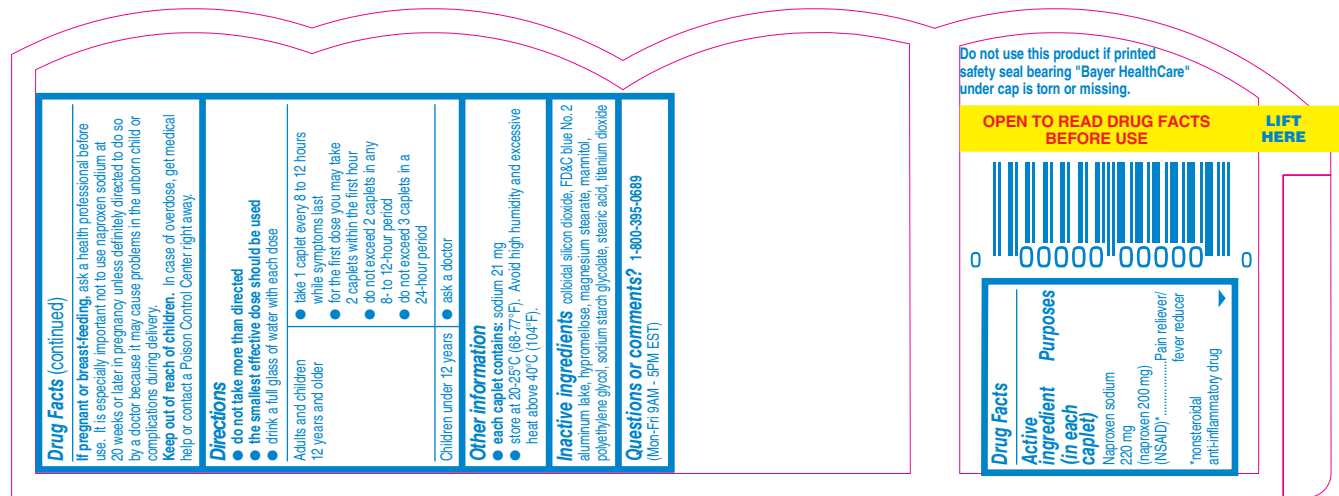
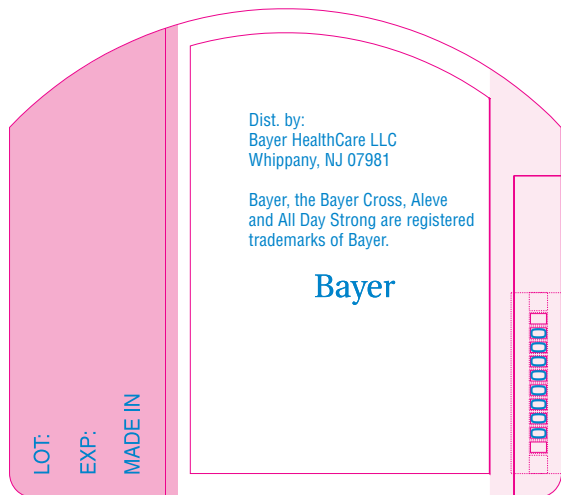


200%



Actual Size 100%

FDA00310-1



Actual Size 100%

FDA43363-0

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 ¹	8 pt-bold italic ²	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

¹ Headings are to be at least 2pts larger than Body Text.

² Drug Facts Title to be larger than a) other type size used in DFP

† FDA Recommends 2 to 3pt rule



Actual Size 100%

FDA45101-2

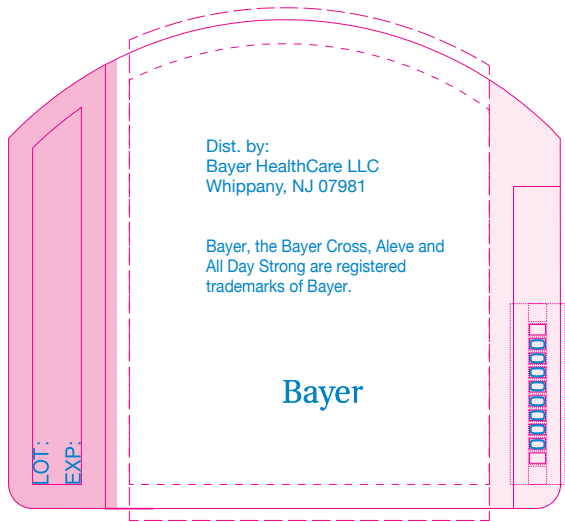
DRUG FACTS INFO Updated 5/18/19		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ¹	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings ¹	8 pt, bold/italic ²	8 pt
Subheadings	>8 pt	8 pt
Body Text	>8 pt	8 pt
Bullets	8 pt	12 pt
Leading	>0.5 pt	1 pt
Headlines	0.5 pt rule	0.5 pt
Box and Border ³	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 35	≥ 39

¹ Headings are to be at least 30pt larger than Body Text.
² Drug Facts Title to be larger than all other type size used in DFP
³ FDA Recommendation: 2.5pt min

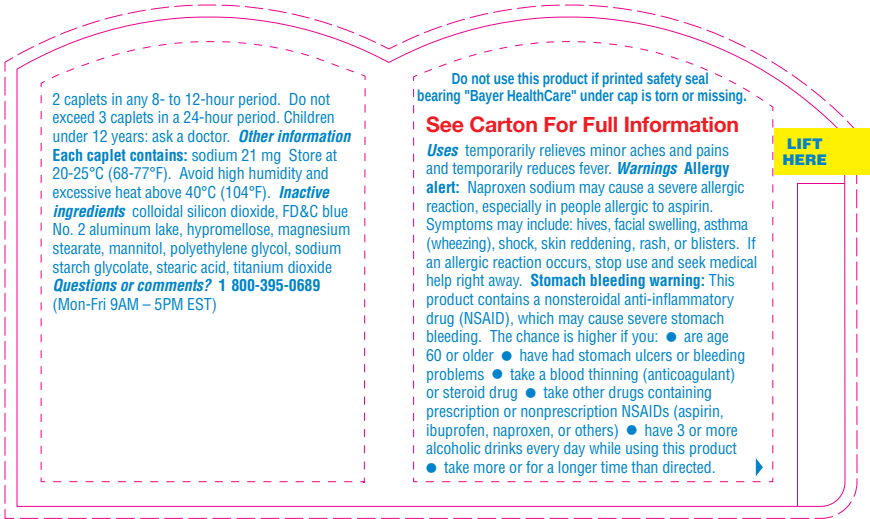


Actual Size 100%

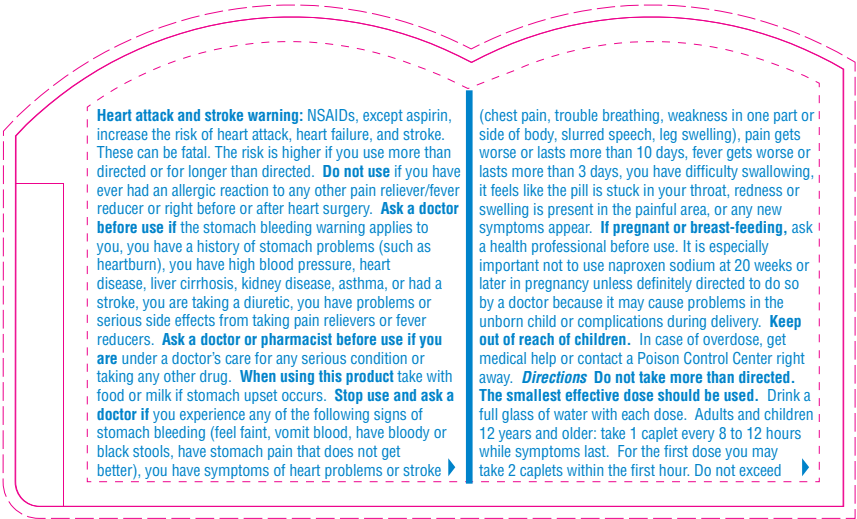
FDA00292-1



BASE



FRONT COVER



INSIDE COVER

Actual Size 100%

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 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		

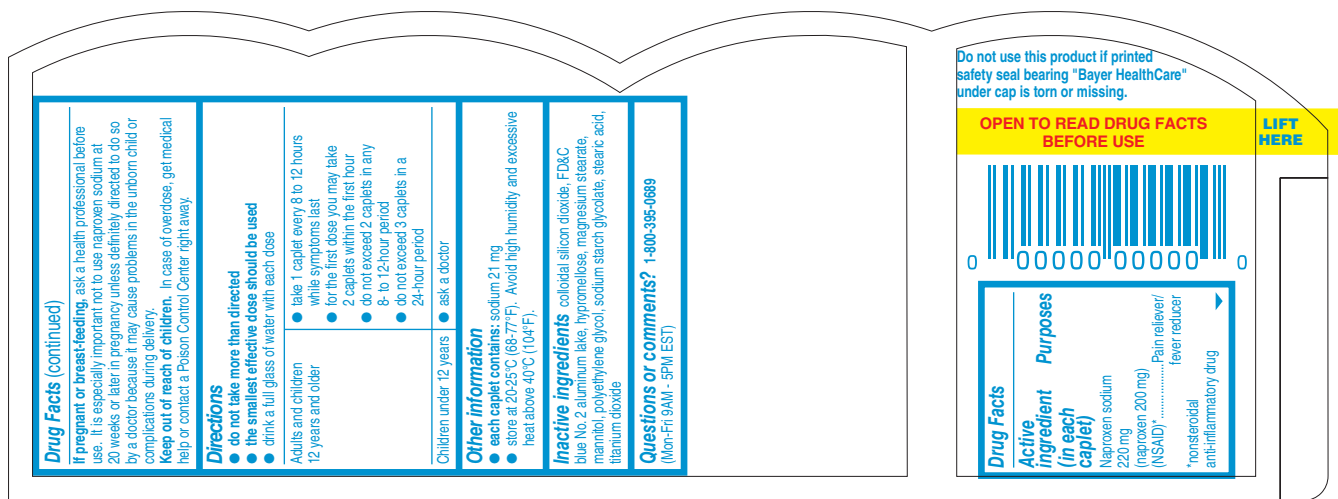
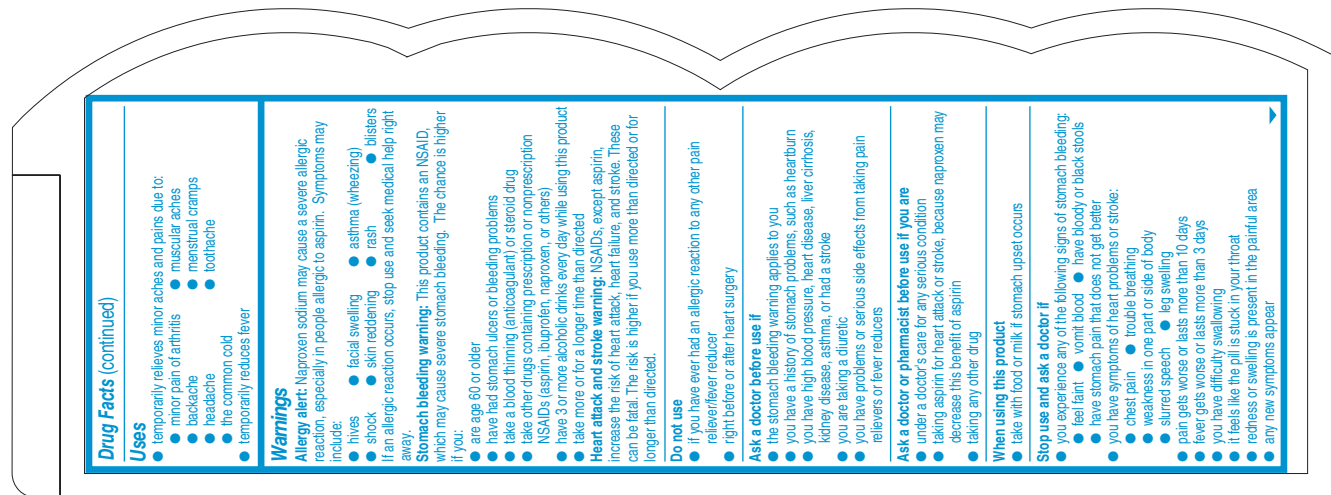
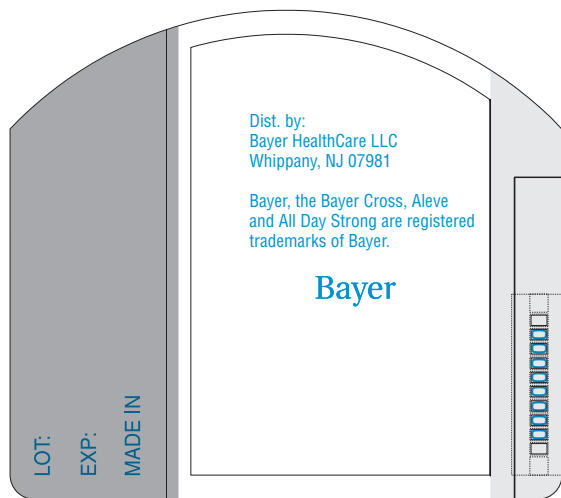


200%



Actual Size 100%

FDA00307-3

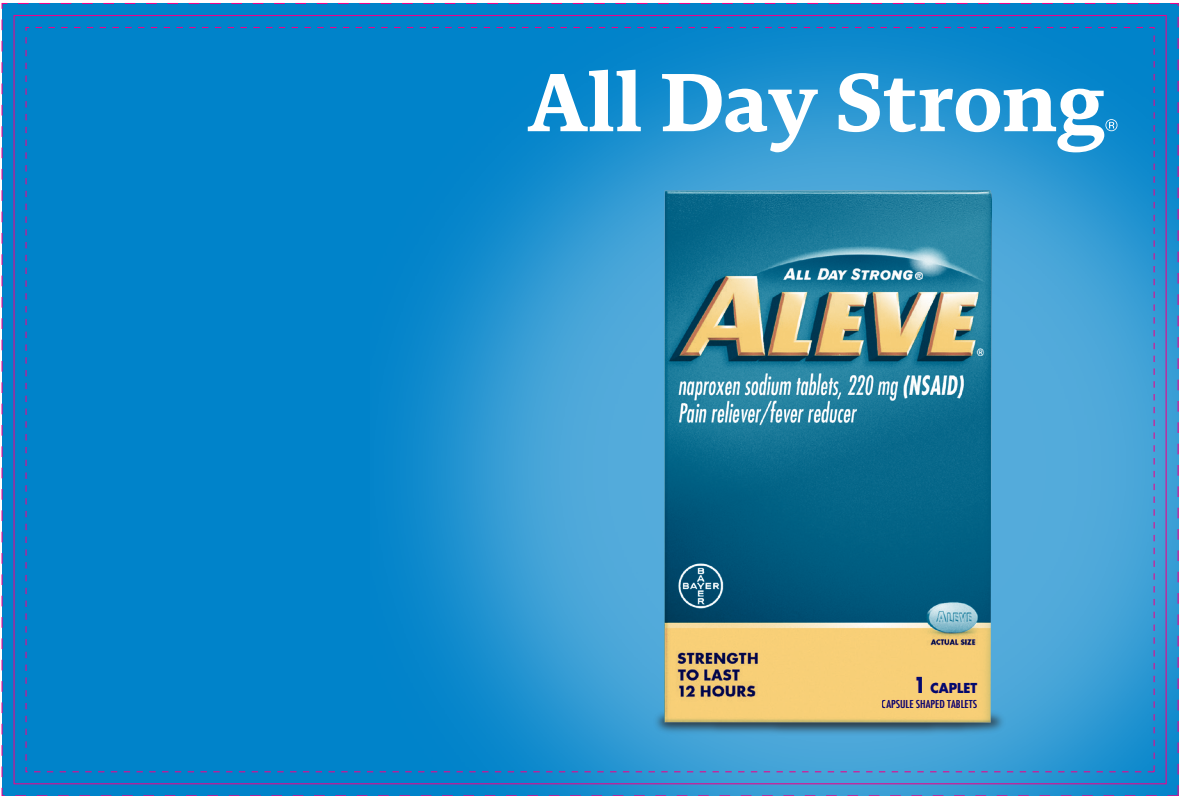


Actual Size 100%

DRUG FACTS INFO (updated 5/19/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ^{a,b}	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings ^c	8 pt bold italic ^b	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 ^d	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

^a Headings are to be at least 2x's larger than Body Text.
^b Drug Facts Title to be larger than all other type size used in DFP
^c FDA Recommendations 2-5 pt rule

FDA-40356-1



Drug Facts

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

Purposes

Uses

- temporarily relieves minor aches and pains due to:
 - minor pain of arthritis
 - muscular aches
 - 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
- asthma (wheezing)
- skin reddening

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.

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
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - 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

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

Children under 12 years

- ask a doctor

Other information

- each caplet contains: sodium 21 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

Inactive ingredients colloidal silicon dioxide, FD&C blue No. 2 aluminum lake, hypromellose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, 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
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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 <i>italic</i> †	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

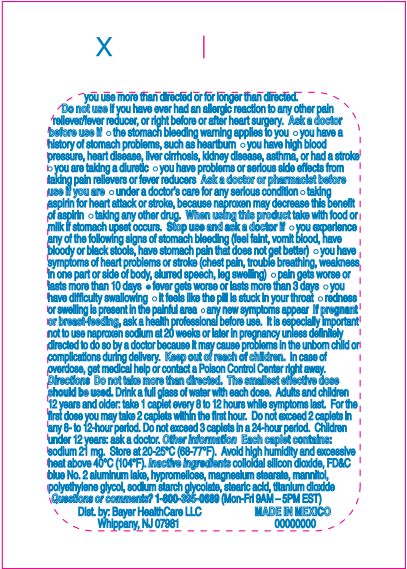
Reference ID: 5152904



Actual Size 100%

FDA48039-2

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 [‡]	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		



Actual Size 100%

FDA48116-2

ICL (updated 3/29/21)		
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 pt
Headlines	0.5 pt rule	-
Bar lines†	> 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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For current labeling information, please visit <https://www.fda.gov/drugsatfda>**

All Day Strong®

MANUFACTURER'S COUPON EXPIRES 00/00/0000

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.

000000-000000

Drug Facts Active ingredient (in each caplet) Naproxen sodium 200 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 - menstrual cramps - toothache - backache - headache - the common cold - temporarily reduces fever	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 - 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
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: Ask naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: - hives - asthma (wheezing) - skin reddening - facial swelling - shock - 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.	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 Children under 12 years - ask a doctor Other information - each caplet contains: sodium 21 mg - store at 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F). Inactive ingredients colloidal silicon dioxide, FD&C blue No. 2 aluminum lake, hypromellose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide Questions or comments? 1-800-355-0689 (Mon - Fri 9AM - 5PM EST) DO NOT USE IF POUCH IS TORN OR OPEN. Bayer, the Bayer Cross, Aleva and All Day Strong are registered trademarks of Bayer. Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981 ©2020 Bayer 00000000 Bayer

Actual Size 100%

FDA44941-5

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 ^a	8 pt-bold italic ^a	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 ^c	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 39	<39

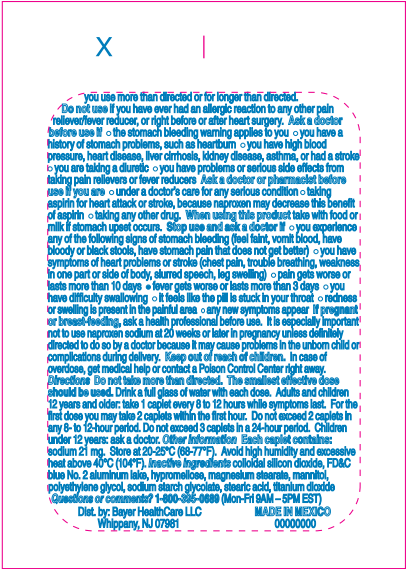
^a Headings are to be at least 20% larger than Body Text.
^b Drug Facts Title to be larger than all other type size used in ODP
^c FDA Recommends 2.5 pt rule



Actual Size 100%

FDA48042-2

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 [‡]	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		



Actual Size 100%

FDA48116-2

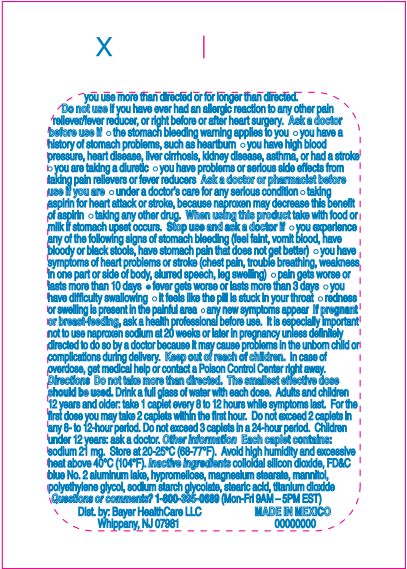
ICL (updated 3/29/21)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt [§]	-
Drug Facts Continued	7 pt [‡]	-
Headings	7 pt- bold italic [‡]	4.5 pt
Subheadings	6 pt [‡]	4.5 pt
Body Text	6 pt [‡]	4.5 pt
Bullets	5 pt	5 pt
Headlines	0.5 pt rule	-
Bar lines [†]	> 0.5 pt rule	-
Characters per 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%

FDA48115-2

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. ^a 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%

FDA48116-2

ICL (updated 3/29/21)		
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 pt
Headlines	0.5 pt rule	-
Bar lines†	> 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%

FDA45090-2

DRUG FACTS INFO		
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	8 pt	12 pt
Leading	>0.5 pt	0.5-0.5 pt
Min size	0.5 pt min	0.5 pt
Box and Barlines†	>0.5 pt min	0.5 pt
Characters Per Inch	No more than 28†	<28

† Drug Facts Title is larger than all other text and is 10 pt
‡ FDA Requirements 2.5 pt min

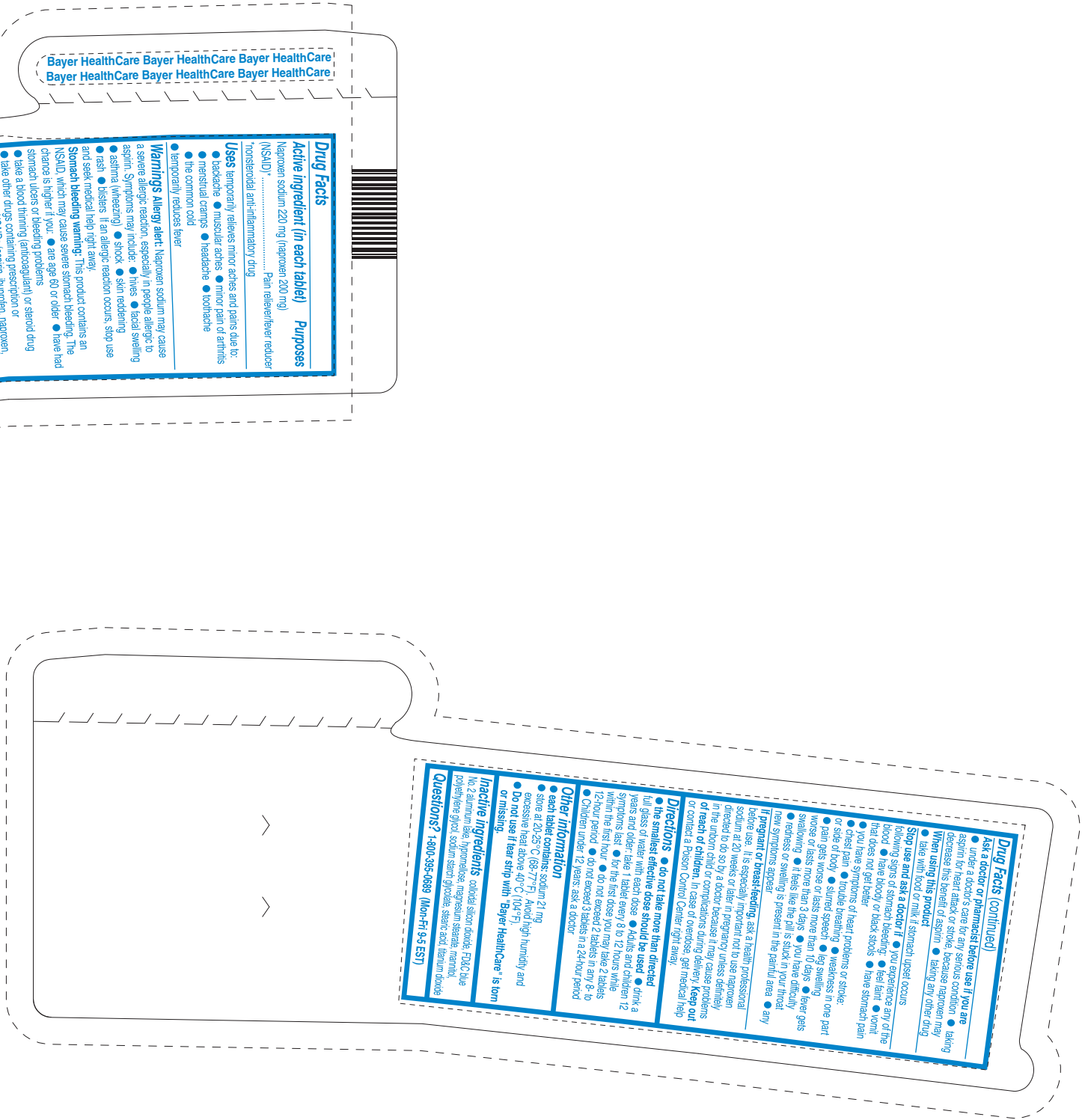
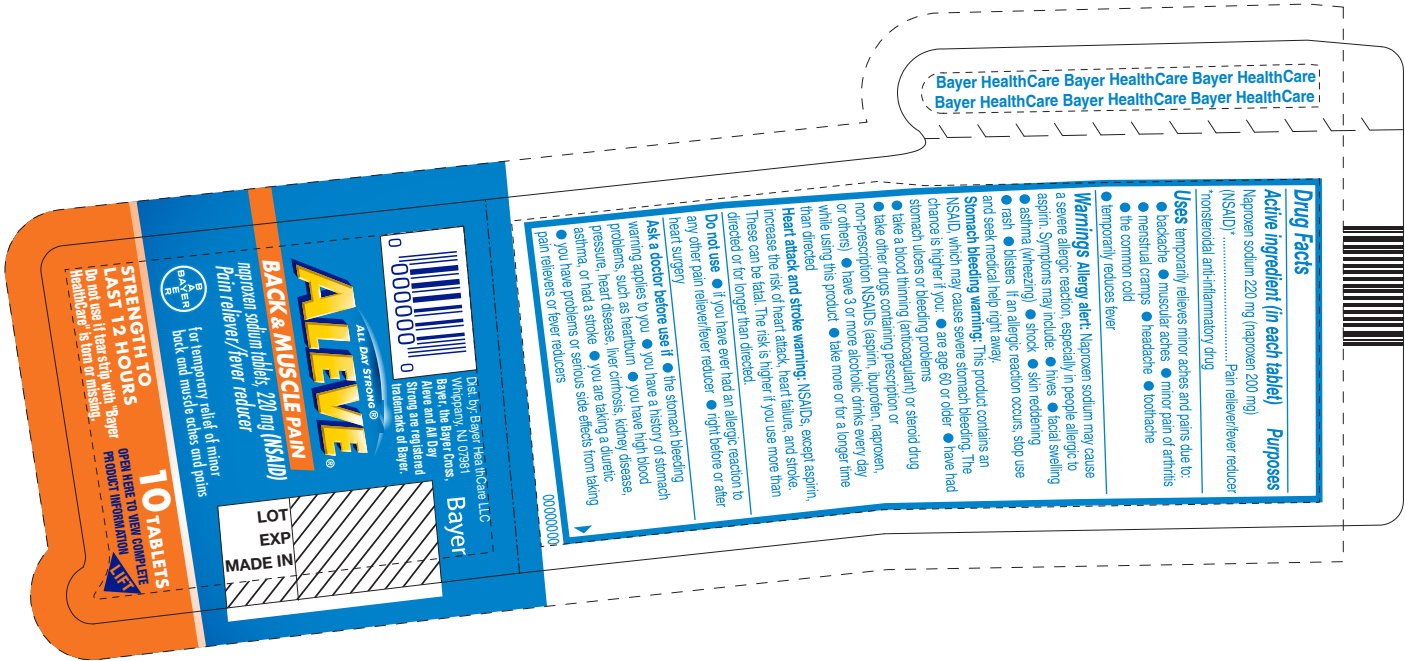


Actual Size 100%

FDA45095-2

DRUG FACTS INFO (Updated 5/18/2023)		
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	<8 pt	8 pt
Body Text	<8 pt	8 pt
Bullets	8 pt	12 pt
Leading	<0.5 pt	0.5-0.5 pt
Min size	0.5 pt min	0.5 pt
Box and Barlines¶	<0.5 pt min	0.5 pt
Characters Per Inch	No more than 28†	<28

† Drug Facts Title is larger than all other text and is 8 pt
‡ FDA Requirements 2.5pt min



Actual Size 100%

FDA-40365-3

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	1/2 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



Actual Size 100%

FDA40027-3

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 - 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 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 DFP
[†] FDA Recommends 2.5pt rule



Actual Size 100%

FDA45214-3

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 pt - 0.5 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barline†	>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		



Actual Size 100%

FDA45217-3

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.
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		



Actual Size 100%

FDA45250-2

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 a 10 pt. type size used in DPP.
† FDA Recommends 2.5pt. rule.



Actual Size 100%

FDA45150-2

DRUG FACTS INFO Updated: 5/18/18		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ¹⁴	9 pt
Drug Facts Continued	8 pt	8 pt
Headings ^a	8 pt-bold-italic ^b	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 ^c	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 30	<30

^a Headings are to be at least 24pt larger than Body Text.
¹⁴ Drug Facts Title to be larger than all other type size used in DPP.
^b FDA recommends 2.5pt rule.

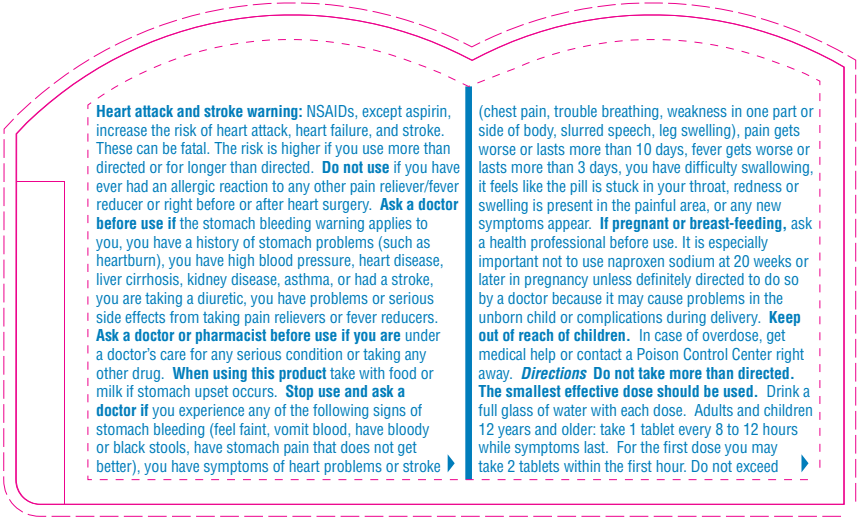
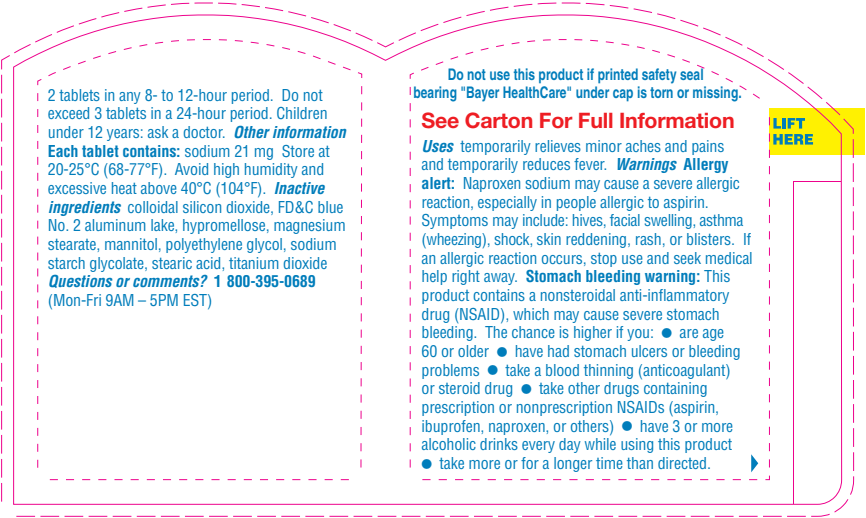
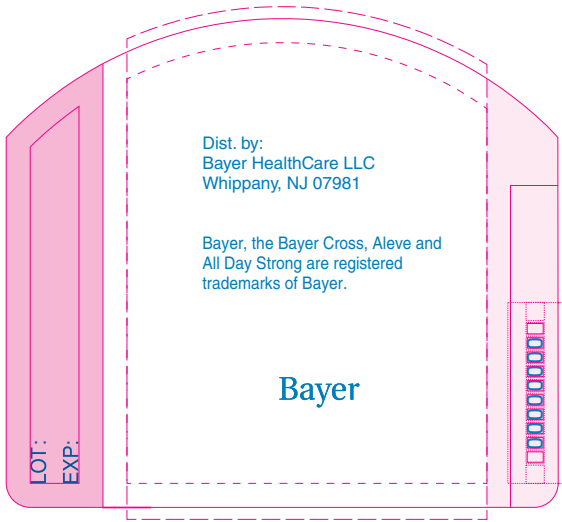


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Actual Size 100%

FDA00277-3



Actual Size 100%

FDA45152-5

DRUG FACTS INFO: (Modified Format – updated 5/18/18)		
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		



Actual Size 100%

FDA45154-2

DRUG FACTS INFO Updated: 5/18/18		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ¹⁴	9 pt
Drug Facts Continued	8 pt	8 pt
Headings ^a	8 pt-bold-italic ^b	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 ^c	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 30	<30

^a Headings are to be at least 24pt larger than Body Text.
¹⁴ Drug Facts Title to be larger than all other type size used in DPP.
^b FDA recommends 2.5pt rule.

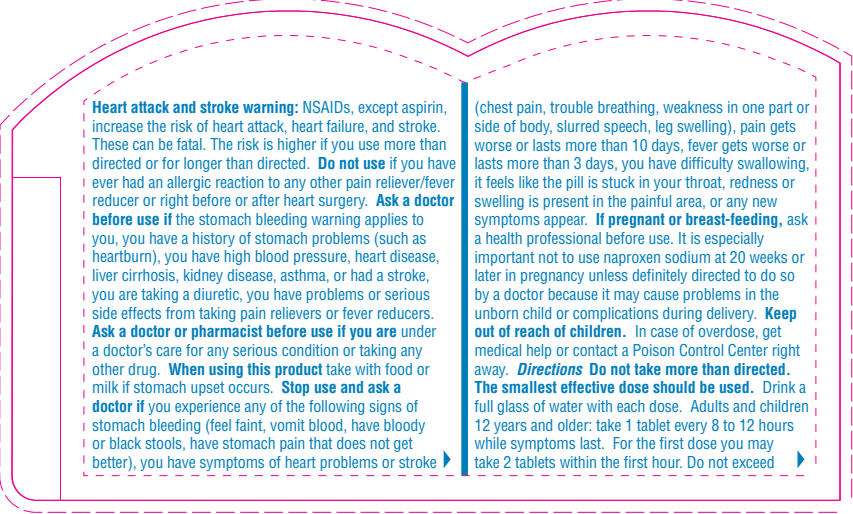
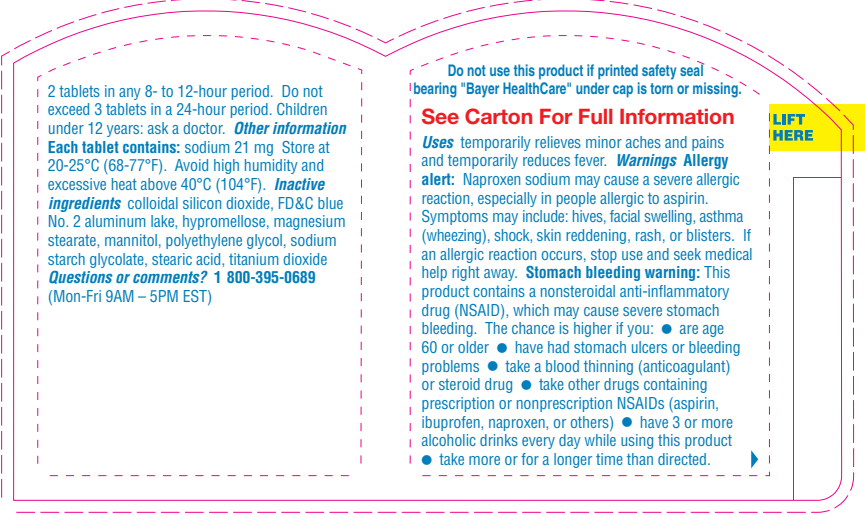
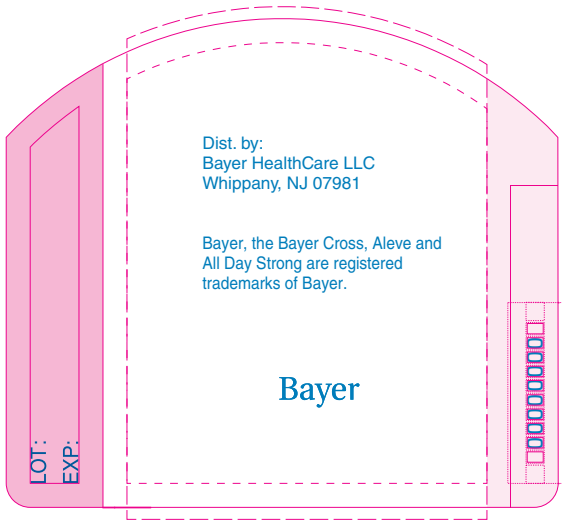


200%



Actual Size 100%

FDA00299-1



Actual Size 100%

FDA45152-5

DRUG FACTS INFO: (Modified Format – updated 5/18/18)		
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		

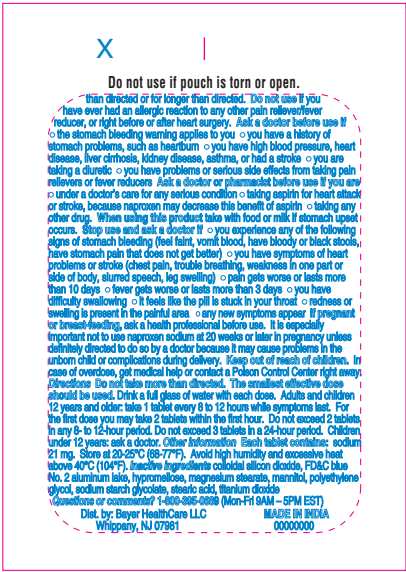


Actual Size 100%

FDA48050-3

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		

100%



Actual Size 100%



Actual Size 100%

FDA40321-2

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



Actual Size 100%

FDA45252-2

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	6.0 - 6.5 pt
Headlines	0.5 pt rule	0.5 pt
Box and Barline†	>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		



Actual Size 100%

FDA45254-3

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.
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 DFP.
† FDA Recommends 2.5pt. rule.



Actual Size 100%

FDA45256-4

DRUG FACTS INFO (updated 5/18/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ^{1,2}	9 pt
Drug Facts Continued	8 pt	8 pt
Headings ¹	8 pt-bold <i>italic</i> ²	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
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 38	≤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 DFP
³ FDA recommends 2-Spt rule

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/s/

NUSHIN F TODD
04/04/2023 10:13:58 AM