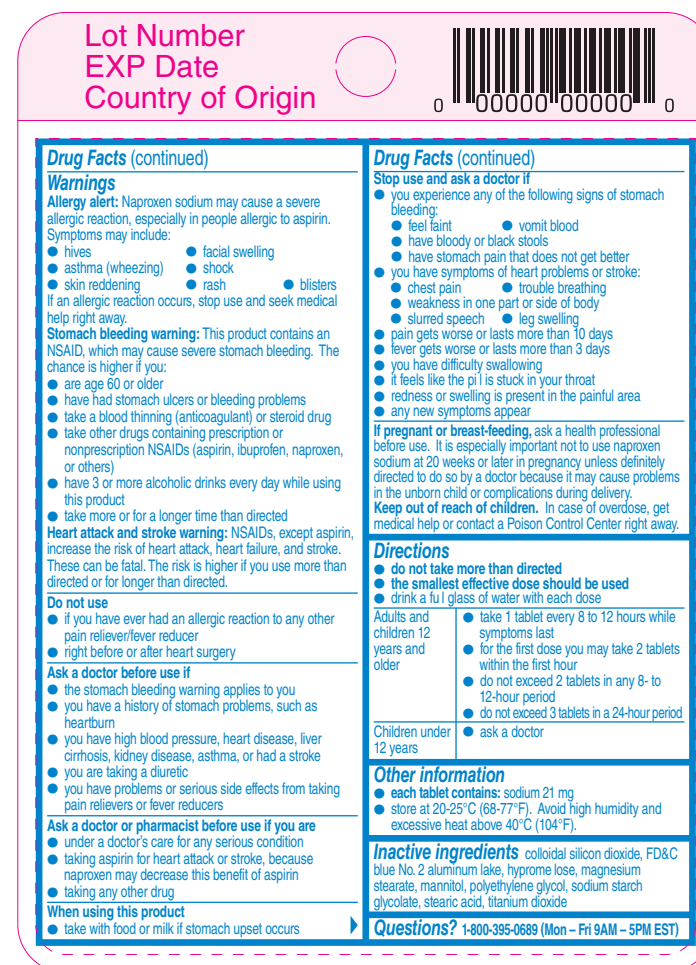




FRONT



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%

FDA40323-2

DRUG FACTS INFO <small>Updated 5/18/18</small>		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt ¹	8.1 pt
Drug Facts Continued	8 pt	8 pt
Headings ²	8 pt-bold italic ³	8 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0.5 pt	0 pt - 0.5 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines ⁴	>0.5 pt rule	2.5 pt
Characters Per Inch	No more than 38	≤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 DPP
³ 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.
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%

FDA47724-1

DRUG FACTS INFO Updated 5/18/18		
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 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 ²	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

¹ Headings are to be at least 6 pts larger than Body Text.
² Drug Facts Title to be larger than all other type size used in DFP.
³ FDA Recommends 2.5 pt. 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 at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

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

Directions

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

Other information

- each tablet contains: sodium 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?

1-800-995-0689 (Mon - Fri 9AM - 5PM EST)

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Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981

Bayer

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LOT EXP MADE IN



STRENGTH TO LAST 12 HOURS

ACTUAL SIZE

90 TABLETS



Actual Size 100%

FDA47729-1

DRUG FACTS INFO Updated 5/18/18		
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 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 ²	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

¹ Headings are to be at least 6 pts larger than Body Text.
² Drug Facts Title to be larger than all other type size used in DFP
³ FDA Recommends 2.5 pt. rule

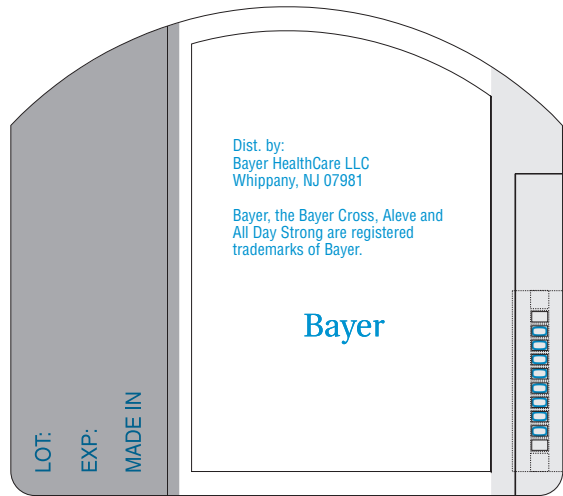


200%



Actual Size 100%

FDA00274-5



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

OPEN TO READ DRUG FACTS BEFORE USE

LOT#
MFG#

0 00000 00000 0

Drug Facts
Active Ingredient (in each tablet)
Naproxen sodium (naproxen 200 mg) (NSAID)
Purpose
Pain reliever/fever reducer
nonsteroidal anti-inflammatory drug

Drug Facts (continued)
If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a health professional. Some uses may cause problems in the unborn child or complications during or after pregnancy.
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 more than 2 tablets in any 8- to 12-hour period.**
● **Do not exceed 3 tablets in a 24-hour period.**
● **Do not take if you are allergic to any of the ingredients listed below.**
● **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 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 21 mg of sodium.
● store at controlled room temperature (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, hydroxymethylcellulose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or Comments? 1-800-555-0899 (Mon - Fri 9AM - 5PM EST)

Uses
● temporarily relieves minor aches and pains due to:
● minor pain of arthritis
● muscle cramps
● headache
● 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
● asthma (wheezing)
● skin redness
● facial swelling
● shock
● rash

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, or
● 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.
● right before or after heart surgery

Ask a doctor before use if
● the stomach bleeding warning applies to you
● you have a history of stomach problems, such as heartburn
● you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
● you have 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: black stools, blood in stool, or dark stools
● you have stomach pain that does not get better
● you have symptoms of heart problems or stroke:
● chest pain ● trouble breathing
● weakness in one part or side of body
● slurred speech ● leg swelling
● pain gets worse or lasts more than 10 days
● you have difficulty swallowing
● you have difficulty swallowing
● if feels like the pill is stuck in your throat
● redness or swelling is present in the painful area
● any new symptoms appear

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 ³	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†	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 38	≤39

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

FDA-40353-1



Actual Size 100%

FDA45166-2

DRUG FACTS INFO	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	>8 pt	8 pt
Body Text	>8 pt	8 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 24pt larger than Body Text.
 †† Drug Facts Title to be larger than all other type size used in ODP.
 ‡ FDA Recommends 2-3pt rule.

Drug Facts (continued)
 Stop use and ask a doctor if:
 • you experience any of the following signs of stomach bleeding:
 • feel faint • vomit blood • have bloody or black stools
 • have stomach pain that does not get better
 • you have symptoms of heart problems or stroke:
 • chest pain • trouble breathing • weakness in one part or side of body
 • slurred speech • leg swelling
 • pain gets worse or lasts more than 10 days
 • fever gets worse or lasts more than 3 days
 • you have difficulty swallowing
 • it feels like the pill is stuck in your throat
 • redness or swelling is present in the painful area
 • any new symptoms appear
 If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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

Adults and children 12 years and older
 • take 1 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 colloidal silicon dioxide, FD&C blue No. 2 aluminum lake, hydroxypropyl methylcellulose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments? 1-800-395-0688 (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.

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

Bayer

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MADE IN
 LOT
 EXP

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

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

STRENGTH TO LAST 12 HOURS
 ACTUAL SIZE
270 TABLETS

STRENGTH TO LAST 12 HOURS
 ACTUAL SIZE
270 TABLETS

0000

QUIET ZONE

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

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

Warnings
Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
 • hives • facial swelling • asthma (wheezing)
 • shock • skin 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 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
Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

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

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

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

When using this product
 • take with food or milk if stomach upset occurs

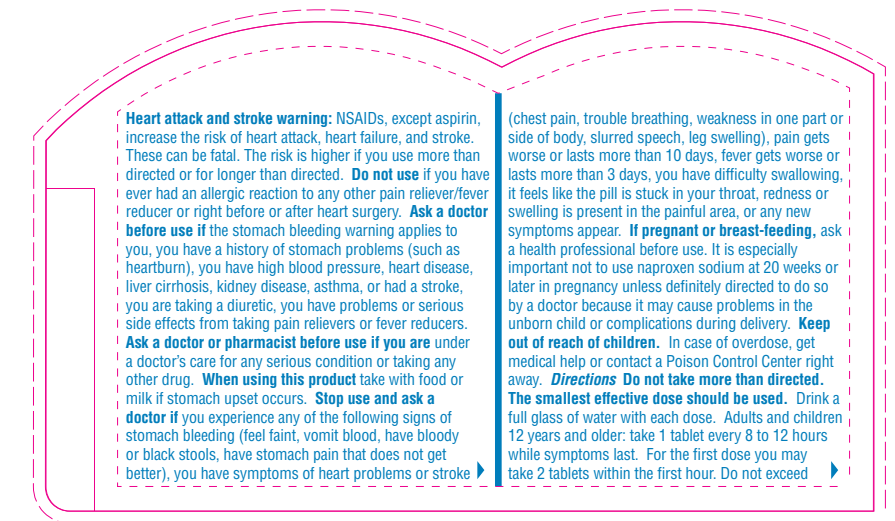
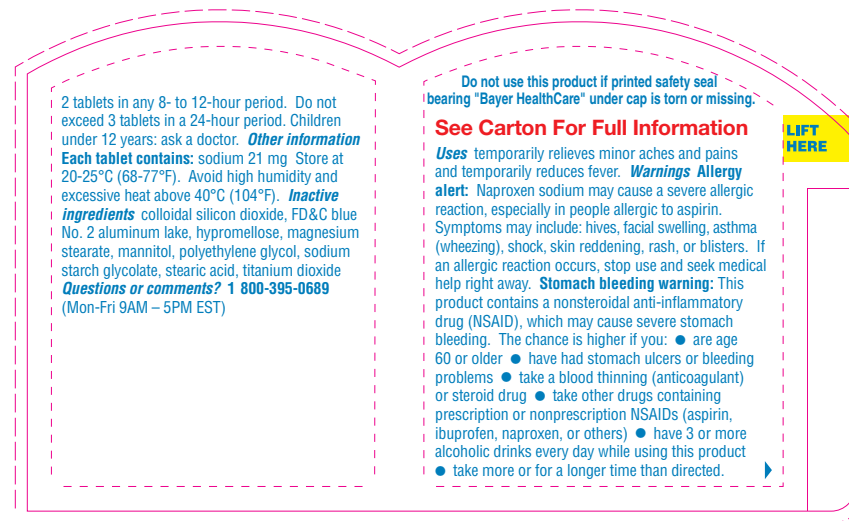
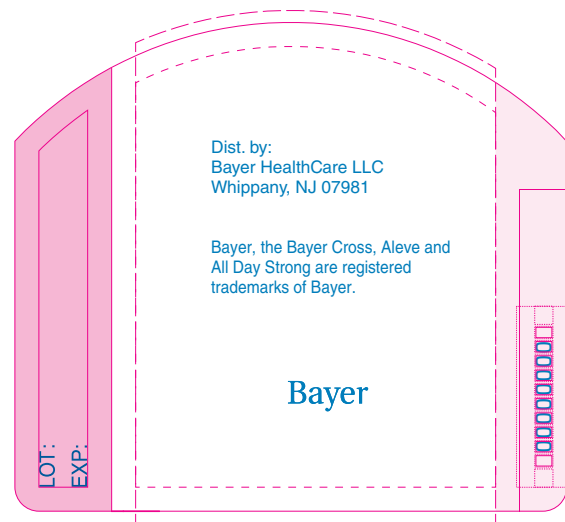


200%



Actual Size 100%

FDA00386-2



Actual Size 100%

FDA45152-5

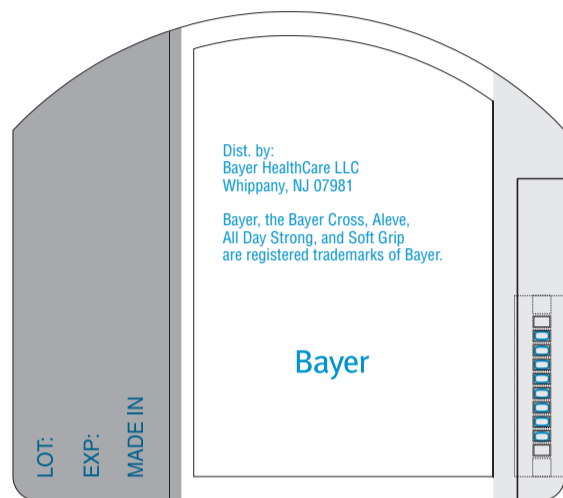
DRUG FACTS INFO: (Modified Format -- updated 5/1/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt-bold italic*	6 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	≥0 pt	1 pt
Hairlines	0.5 pt rule	-
Box and Barlines†	>0.5 pt rule	-
Characters Per Inch:	No more than 39	≤39

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



Actual Size 100%

FDA00300-1



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

OPEN TO READ DRUG FACTS BEFORE USE

Drug Facts (continued)

Warnings

- **Do not take more than directed**
- **the smallest effective dose should be used**

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
- keep 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? 1-800-858-0888 (Mon-Fri 9AM-5PM EST)

Drug Facts

Active Ingredient (In each tablet): Naproxen sodium 220 mg (naproxen 200 mg)

Purpose: 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
 - backache
 - menstrual cramps
- headache
- the common cold
- temporary 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 other drugs containing aspirin or other nonsteroidal anti-inflammatory drug (NSAIDs) (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product

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

Do not use

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

Ask a doctor before use if:

- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you are taking aspirin, blood thinners, diuretics, lithium, potassium, sodium, or other drugs
- 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 use:

- 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

What makes this product different?

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if: Following signs of stomach bleeding:

- you feel any of the following:
 - signs of stomach bleeding: black stools, blood in stool, 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
- liver gets worse or lasts more than 3 days
- you have difficulty swallowing
- you have difficulty breathing
- redness or swelling is present in the painful area
- any new symptoms appear

Actual Size 100%

FDA-40363-3

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	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	12 pt
Leading	>0.5 pt	0.5 pt
Hairlines	0.5 pt rule	0.5 pt
Box and Barlines [†]	>0.5 pt rule	2.5 pt
Characters Per Inch:	No more than 39	≤39

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



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. **	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.	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 38	≤ 39

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



Actual Size 100%

FDA40011-3

DRUG FACTS INFO <small>Updated 5/18/18</small>		
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 DPP
 † FDA recommends 2-3pt rule

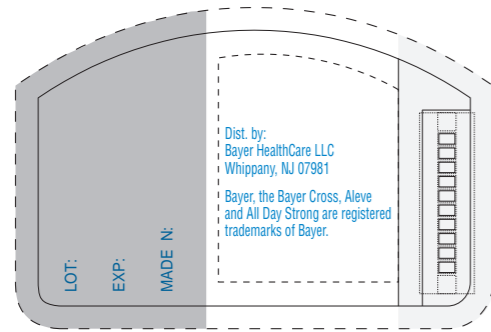


200%



Actual Size 100%

FDA00273-2



Actual Size 100%

FDA-40351-2

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.	12 pt.
Leading	≥0.5 pt.	6 & 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 ODP
 † FDA Recommends 2.5pt rule

Drug Facts (continued)

Uses

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

Warnings

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

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

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

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

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

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

Do not use

- if you have ever had an allergic reaction to any other pain reliever or aspirin
- 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:
 - black, tarry stools
 - blood or black stools
 - have stomach pain that does not get better

Drug Facts (continued)

- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - trouble seeing
 - one arm or leg is weaker or less coordinated than the other
 - one eye is larger or less than the other
 - you have difficulty swallowing
 - it feels like the pill is stuck in your throat
 - redness or swelling is present in the painful area
 - any new symptoms appear

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

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

Directions

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

Adults and children 12 years and older

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

Children under 12 years

Other Information

- each white 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

croscellose, hydroxypropyl methylcellulose, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

1-800-525-0888 (Mon-Fri 9AM - 5PM EST)

Bayer

Drug Facts

Keep this information in each caplet. Progression of symptoms may vary. For more information, see the back of the caplet. Do not use if the caplet is damaged or if the caplet is not in its original packaging.

Keep out of reach of children. See important information on Bayer logo.



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.
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%

FDA45169-3

DRUG FACTS INFO <small>Updated 5/18/18</small>		
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.	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 38	≤ 39

* Headings are to be at least 20% larger than Body Text.
 ** Drug Facts Title is to be larger than all other type size used in DFP.
 † 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
- any new symptoms appear

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

Drug Facts (continued)

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

Directions

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

Adults and children 12 years and older

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

Children under 12 years

- ask a doctor

Other information

- each caplet contains: sodium 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)

Dist. by:
 Bayer HealthCare LLC
 Whippany, NJ 07981

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Bayer

NI 3GVW 4X3 401

SOFT GRIP® ARTHRITIS CAP

ALL DAY STRONG®

ALEVE

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

SOFT GRIP® ARTHRITIS CAP

ALL DAY STRONG®

ALEVE

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

THIS PACKAGE IS CHILD-RESISTANT

BAYER

ACTUAL SIZE

50 CAPLETS
 CAPSULE-SHAPED TABLETS

STRENGTH TO LAST 12 HOURS

0 000000 000000 0

Drug Facts

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

Purposes

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

Warnings

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

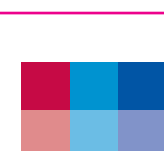
- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

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

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

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 5 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.





Actual Size 100%

FDA45183-3

DRUG FACTS INFO Updated 5/18/18		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ^{1*}	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings [†]	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 [‡]	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

¹ Headings are to be at least 6 pts larger than Body Text.
[†] Drug Facts Title to be larger than all other type size used in DFP.
[‡] FDA Recommends 2.5pt. 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 at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

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

Directions

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

Adults and children 12 years and older

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

Children under 12 years

- ask a doctor

Other information

- each caplet contains: sodium 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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ALL DAY STRONG
ALEVE

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

ALL DAY STRONG
ALEVE

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



STRENGTH TO LAST 12 HOURS

ACTUAL SIZE

90 CAPLETS
 CAPSULE-SHAPED TABLETS

LOT EXP MADE IN



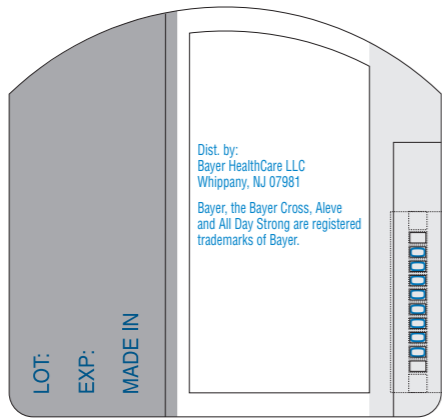


200%



Actual Size 100%

FDA00272-2



Drug Facts (continued)

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you get a rash or hives
- it feels like there is something 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 during pregnancy because it may harm the unborn child. Notify your health care provider if you are pregnant or planning to get pregnant, because there are some risks to 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 amount effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

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

Children under 12 years

Other Information

- each caplet contains sodium 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? 1-800-368-0888 (Non-FDA - SP-EST)

Bayer

Drug Facts

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

Do not use this product if you are allergic to any of the ingredients listed above or to any of the other ingredients listed in the inactive ingredients section of this Drug Facts label.

Drug Facts (continued)

Uses

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

Warnings

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

- hives
- facial swelling
- rash
- skin redness/itching
- asthma (wheezing)
- shock
- 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. **Black tarry stools and blood in the stool or urine.** Stomach, intestinal, and kidney bleeding may occur without warning and may 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 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:

- taking aspirin or other NSAIDs, except for low-dose aspirin for heart disease 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
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain or heartburn that does not get better
 - notice a change in your stool, such as black or tarry stools
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling

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	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 - 0.7 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

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



Actual Size 100%

FDA45222-2

DRUG FACTS INFO Updated 5/18/18		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt. ¹	9 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings 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 ²	>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.
² Drug Facts Title to be larger than all other type size used in DFP.
³ FDA Recommends 2 Sp. 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 at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Drug Facts (continued)

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

Directions

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

Other information

- each caplet contains: sodium 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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ALL DAY STRONG
ALEVE

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

20 FREE CAPLETS WITH THIS PURCHASE

ALL DAY STRONG
ALEVE

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



STRENGTH TO LAST 12 HOURS

ACTUAL SIZE
110
90
CAPSULE-SHAPED TABLETS

LOT EXP MADE IN

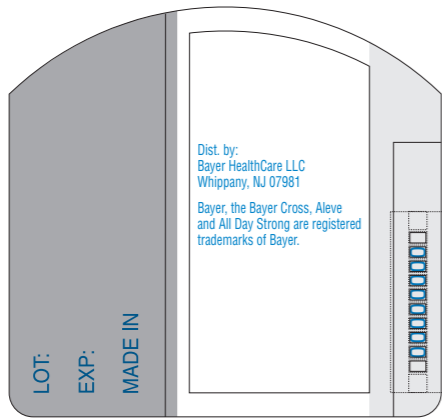


200%



Actual Size 100%

FDA00373-2



Drug Facts (continued)

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- you have a rash or hives
- it feels like there is something 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 during pregnancy because it may harm the fetus. It may also be harmful to a fetus if a doctor has previously diagnosed to do so. Do not use if you have had any of the following 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 amount effective dose should be used
- drink a full glass of water with each dose

Adults and children 12 years and older

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

Children under 12 years

Other Information

- each caplet contains sodium 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? 1-800-368-0888 (Non-FBI/BLM - SP/EST)

Bayer

Drug Facts

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

Do not use this product if you are allergic to any of the ingredients listed above or to any of the ingredients listed below. See the ingredient list on the back of this package for more information.

Drug Facts (continued)

Uses

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

Warnings

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

- hives
- facial swelling
- rash
- skin redness/itching
- asthma (wheezing)
- shock
- 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. **Black tarry stools and blood in the stool or urine.** Stomach, intestinal, and kidney bleeding may occur without warning and may 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 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:

- taking aspirin or other NSAIDs, except for low-dose aspirin for heart disease, 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
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain or heartburn and get better only when taking antacids
 - cough up blood
 - black stool
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling

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	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 - 0.7 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

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



Actual Size 100%

FDA45181-2

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 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.	0.8 pt.
Hairlines	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 6 pts. larger than Body Text.
^{**} Drug Facts Title to be larger than all other type size used in DFP.
¹ FDA Recommends 2.5pt. rule.

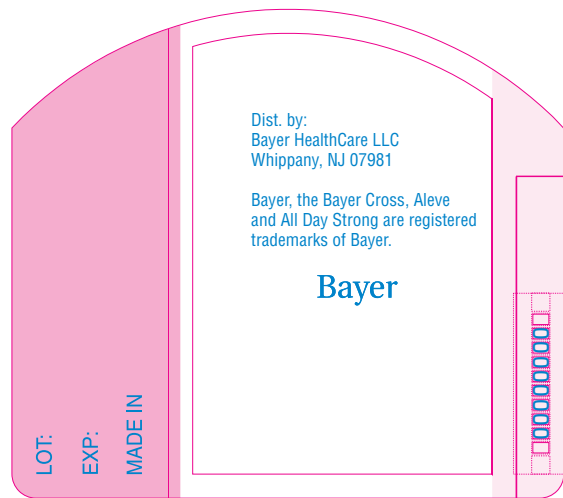


200%



Actual Size 100%

FDA00310-1



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

OPEN TO READ DRUG FACTS BEFORE USE **LIFT HERE**

0 00000 00000 0

Drug Facts

Active ingredient (in each caplet)
Naproxen sodium 220 mg
(NSAID).....pain reliever/
fever reducer
ibuprofen 200 mg.....pain reliever/
fever reducer
acetaminophen 325 mg.....antiflammatory drug

Purposes

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, microcrystalline cellulose, polyethylene glycol, sodium acetate, sodium hydroxide, stearic acid, titanium dioxide

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

Drug Facts (continued)

Uses

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

Warnings

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

- hives
- facial swelling
- asthma (wheezing)
- swelling
- 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 recommended

Heart failure warning: Heart failure (CHF), heart failure, or congestive heart failure may be worsened by NSAIDs, except aspirin. These may include swelling, increased weight, and shortness of breath. The risk is higher if you use more than directed or for longer than directed.

Do not use

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

Ask a doctor before use if

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

Ask a doctor or pharmacist before use if you are

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

When using this product

- take with food or milk, if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - black stools
 - dark red stools
 - stomach pain that does not go away
- 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

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†	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 38	≤39

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



Actual Size 100%

FDA45101-2

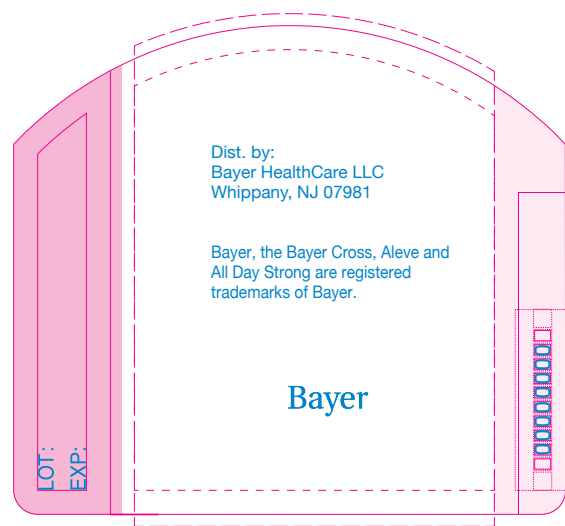
DRUG FACTS INFO	REQUIRED	ACTUAL IN FILE
Category	REQUIRED	ACTUAL IN FILE
Drug Facts Table	>8 pt. ¹¹	8.1 pt.
Drug Facts Continued	8 pt.	8 pt.
Headings*	8 pt./bold table ¹	8 pt.
Subheadings	>8 pt.	8 pt.
Body Text	>8 pt.	8 pt.
Bullets	5 pt.	12 pt.
Leading	>0.5 pt.	1 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 30	≥ 30

* Headings are to be at least 20pt larger than Body Text.
 † Drug Facts Table to be larger than all other type size used in DPP.
 ‡ FDA Recommendations 2:2017 table

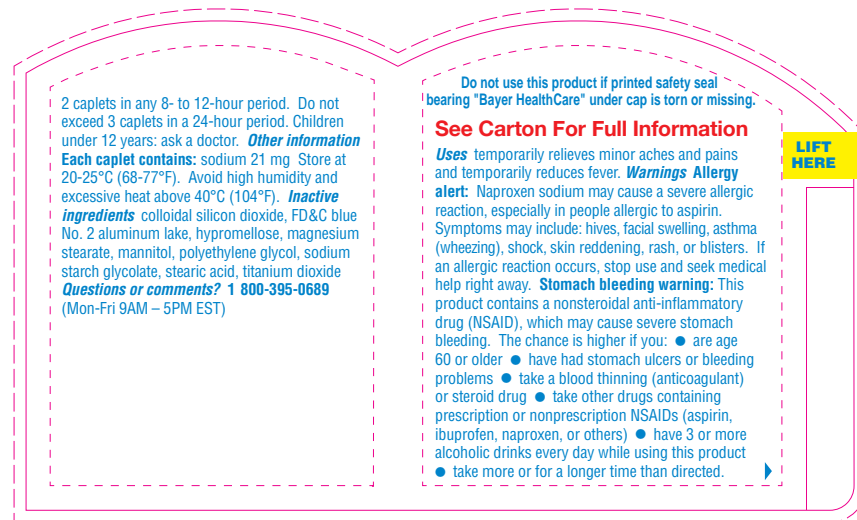


Actual Size 100%

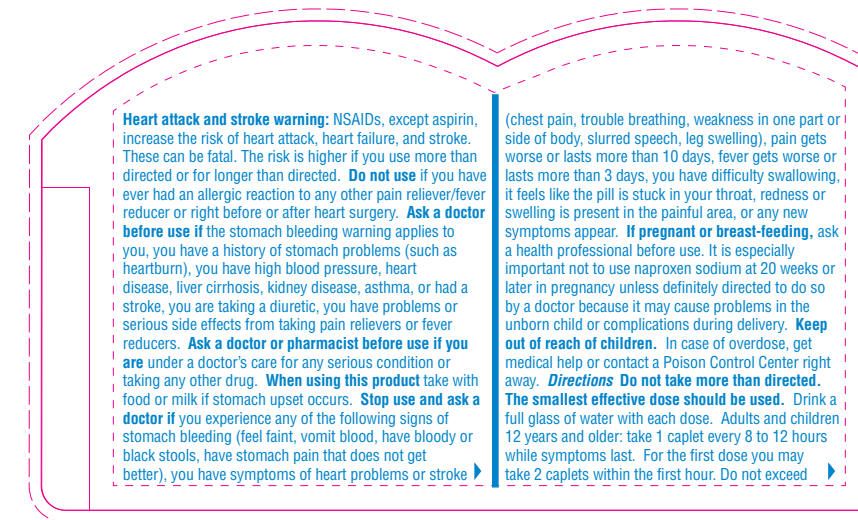
FDA00292-1



BASE



FRONT COVER



INSIDE COVER

Actual Size 100%

FDA45102-1

DRUG FACTS INFO		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>8 pt **	-
Drug Facts Continued	8 pt	-
Headings [†]	8 pt-bold italic [†]	6 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 pt	5 pt
Leading	≥0.5 pt	7 pt
Hair ines	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
[†] FDA Recommends 2.5pt rule

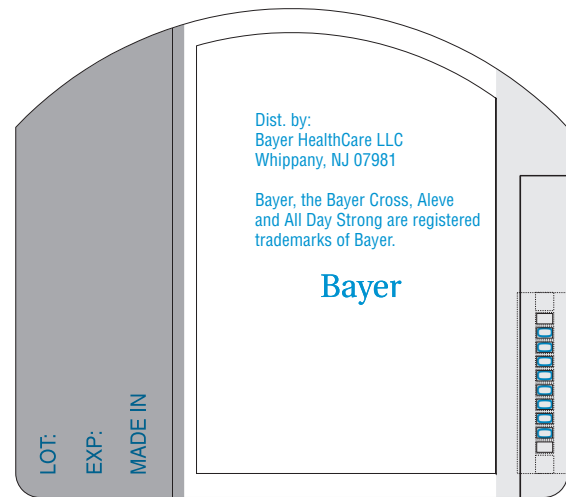


200%



Actual Size 100%

FDA00307-3



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

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

- hives
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- skin rash
- itching

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
- use aspirin or other NSAIDs
- 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

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 of this type
- right before or after heart surgery

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have had heart problems, such as heartburn, indigestion, or acid reflux
- 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
 - trouble speaking
 - 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 26 to 35 weeks of pregnancy 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
- take with food or milk
- 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
- do not take more than 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, hydroxypropylcellulose, magnesium stearate, mannitol, polyethylene glycol, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments? 1-800-365-6689
(Non-FDA/AMA/SPM/ES)

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

OPEN TO READ DRUG FACTS BEFORE USE

LIFT HERE

0 00000 00000 0

Drug Facts

Active Ingredient (in each caplet)

Naproxen sodium
220 mg
(NSAID)*

Purposes

Pain reliever/
fever reducer
anti-inflammatory drug

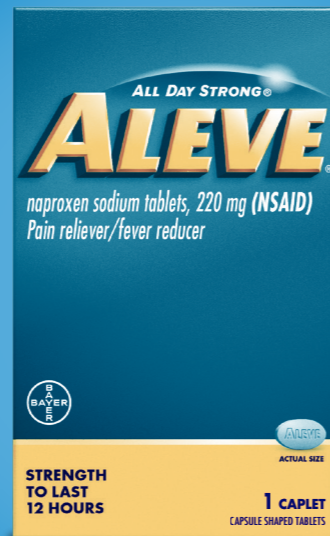
Actual Size 100%

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 DFP
† FDA Recommends 2.5pt rule

FDA-40356-1

All Day Strong®



Drug Facts	Drug Facts (continued)	Drug Facts (continued)
<p>Active ingredient (in each caplet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p>Uses temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> minor pain of arthritis muscular aches menstrual cramps toothache backache headache the common cold temporarily reduces fever</p> <p>Warnings Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> are age 60 or older have had stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) have 3 or more alcoholic drinks every day while using this product take more or for a longer time than directed Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p>	<p>Do not use <ul style="list-style-type: none"> if you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery Ask a doctor before use if <ul style="list-style-type: none"> the stomach bleeding warning applies to you you have a history of stomach problems, such as heartburn you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke you are taking a diuretic you have problems or serious side effects from taking pain relievers or fever reducers Ask a doctor or pharmacist before use if you are <ul style="list-style-type: none"> under a doctor's care for any serious condition taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin taking any other drug When using this product <ul style="list-style-type: none"> take with food or milk if stomach upset occurs Stop use and ask a doctor if <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> feel faint have bloody or black stools have stomach pain that does not get better you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> chest pain weakness in one part or side of body slurred speech leg swelling pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days you have difficulty swallowing it feels like the pill is stuck in your throat redness or swelling is present in the painful area any new symptoms appear </p>	<p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions <ul style="list-style-type: none"> do not take more than directed the smallest effective dose should be used drink a full glass of water with each dose Adults and children 12 years and older <ul style="list-style-type: none"> take 1 caplet every 8 to 12 hours while symptoms last for the first dose you may take 2 caplets within the first hour do not exceed 2 caplets in any 8- to 12-hour period do not exceed 3 caplets in a 24-hour period Children under 12 years <ul style="list-style-type: none"> ask a doctor </p>
	<p>When using this product <ul style="list-style-type: none"> take with food or milk if stomach upset occurs Stop use and ask a doctor if <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> feel faint have bloody or black stools have stomach pain that does not get better you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> chest pain weakness in one part or side of body slurred speech leg swelling pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days you have difficulty swallowing it feels like the pill is stuck in your throat redness or swelling is present in the painful area any new symptoms appear </p>	<p>Other information <ul style="list-style-type: none"> 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</p> <p>Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)</p> <p>DO NOT USE IF POUCH IS TORN OR OPEN. Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer. Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981 ©2020 Bayer 00000000 Bayer</p>

Actual Size 100%

FDA45087-3

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 - 0.7 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines§	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 38	≤39

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



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

X

- you use more than directed or for longer than directed.
- Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. Ask a doctor before use if - the stomach bleeding warning applies to you - you have a history of stomach problems, such as heartburn - you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke - you are taking a diuretic - you have problems or serious side effects from taking pain relievers or fever reducers. Ask a doctor or pharmacist before use if you are - under a doctor's care for any serious condition - taking aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin - taking any other drug. When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor if - you experience any of the following signs of stomach bleeding (stool that is black, 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 genital area - any new symptoms appear. If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **Warnings:** Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 capsule every 8 to 12 hours while symptoms last. For the first dose you may take 2 capsules within the first hour. Do not exceed 2 capsules in any 8- to 12-hour period. Do not exceed 3 capsules in a 24-hour period. Children under 12 years: ask a doctor. Other information: Each capsule 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, croscarmellose sodium, titanium dioxide. **Questions or comments? 1-800-365-0089 (Mon-Fri 9AM - 5PM EST)**
Dist. by: Bayer HealthCare LLC MADE IN MEXICO
Whisper, NJ 07081 0200000

Actual Size 100%

FDA48116-2

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

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

All Day Strong®



MANUFACTURER'S COUPON EXPIRES 00/00/0000

SAVE \$2.00
ON ANY ONE (1) ALEVE®
2OCT. 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.



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
 - backache
 - headache
 - the common cold

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
- 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)

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
- vomit blood

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)

DO NOT USE IF POUCH IS TORN OR OPEN.

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Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981
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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*	8 pt.-bold/italic*	8 pt.
Subheadings	≥6 pt.	6 pt.
Body Text	≥6 pt.	6 pt.
Bullets	5 pt.	12 pt.
Leading	≥0.5 pt.	0.5 - 0.7 pt.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines*	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

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



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

X

- you use more than directed or for longer than directed.
- the nit rate if you have ever had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. Ask a doctor before use if - the stomach bleeding warning applies to you - you have a history of stomach problems, such as heartburn - you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke - you are taking a diuretic - you have problems or serious side effects from taking pain relievers or fever reducers. Ask a doctor or pharmacist before use if you are - under a doctor's care for any serious condition - taking aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin - taking any other drug. When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor if - you experience any of the following signs of stomach bleeding (stool that is black, 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 genital area - any new symptoms appear. If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **Warnings:** Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 capsule every 8 to 12 hours while symptoms last. For the first dose you may take 2 capsules within the first hour. Do not exceed 2 capsules in any 8- to 12-hour period. Do not exceed 3 capsules in a 24-hour period. Children under 12 years: ask a doctor. Other information: Each capsule 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, croscarmellose sodium, titanium dioxide. **Questions or comments? 1-800-365-0089 (Mon-Fri 9AM - 5PM EST)**
Dist. by: Bayer HealthCare LLC MADE IN MEXICO
Whisper, NJ 07081 0200000

Actual Size 100%

FDA48116-2

ICL (updated 3/29/21)	Bayer Standard	ACTUAL IN FILE
Category		
Drug Facts Title	>7 pt ^a	-
Drug Facts Continued	7 pt ^a	-
Headings	7 pt-bold italic ^a	4.5 pt
Subheadings	6 pt ^a	4.5 pt
Body Text	6 pt ^a	4.5 pt
Bullets	5 pt	5 pt
Hairlines	0.5 pt rule	-
Bar lines ^b	> 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.
^b 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 ¹	-
Drug Facts Continued	7 pt ²	-
Headings	7 pt-bold italic ³	4.5 pt
Subheadings	6 pt ³	4.5 pt
Body Text	6 pt ³	4.5 pt
Bullets	5 pt	5.5 pt
Hairlines	0.5 pt rule	-
Barlines ⁴	> 0.5 pt rule	-

¹Characters per inch rule is not applicable to ICL.
²ICL minimum font size is 4.5 pt.
³< 0.5 pt leading may be used as long as ascenders and descenders do not touch.
⁴FDA recommends size 2.5 pt type

X

- you use more than directed or for longer than directed.
- the nit rate if you have ever had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. Ask a doctor before use if - the stomach bleeding warning applies to you - you have a history of stomach problems, such as heartburn - you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke - you are taking a diuretic - you have problems or serious side effects from taking pain relievers or fever reducers. Ask a doctor or pharmacist before use if you are - under a doctor's care for any serious condition - taking aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin - taking any other drug. When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor if - you experience any of the following signs of stomach bleeding (stool that is black, 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 genital area - any new symptoms appear. If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. **Warnings:** Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 capsule every 8 to 12 hours while symptoms last. For the first dose you may take 2 capsules within the first hour. Do not exceed 2 capsules in any 8- to 12-hour period. Do not exceed 3 capsules in a 24-hour period. Children under 12 years: ask a doctor. Other information: Each capsule 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, croscarmellose sodium, titanium dioxide. **Questions or comments? 1-800-365-0089 (Mon-Fri 9AM - 5PM EST)**
Dist. by: Bayer HealthCare LLC MADE IN MEXICO
Whisper, NJ 07081 0200000

Actual Size 100%

FDA48116-2

ICL (updated 3/29/21)		
CATEGORY	Bayer Standard	ACTUAL IN FILE
Drug Facts Title	>7 pt ^a	-
Drug Facts Continued	7 pt ^a	-
Headings	7 pt-bold/italic ^b	4.5 pt
Subheadings	6 pt ^a	4.5 pt
Body Text	6 pt ^a	4.5 pt
Bullets	5 pt	5 pt
Hairlines	0.5 pt rule	-
Bar lines ^c	> 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.
^c FDA recommends size 2.5 pt type



Actual Size 100%

FDA45090-2

CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	≥8 pt	8.1 pt
Drug Facts Content	8 pt	8 pt
Headings*	8 pt bold italic	8 pt
Subheadings	≥8 pt	8 pt
Body Text	≥8 pt	8 pt
Tables	8 pt	10 pt
Footnote	≥8.5 pt	8.5 pt
Header	8.5 pt min	8.5 pt
Box and Banner†	≥0.5 pt min	0.5 pt
Characters Per Inch	10 min (60 DPI)	10.5

*Headings are to be at least 1/8" larger than body text.
†The font size to be larger than all other text used in DPP.
†DPI: Resolutions: 300 min



Actual Size 100%

FDA45095-2

CATEGORY	REQUIREMENT	ACTUAL IN FILE
Drug Facts Title	>8 pt.	8.1 pt.
Drug Facts Content	8 pt.	8 pt.
Headings*	8 pt bold italic	8 pt.
Subheadings	>8 pt.	8 pt.
Body Text	>8 pt.	8 pt.
Bullets	10 pt.	10 pt.
Linking	>8.5 pt.	8.5 pt.
Header lines	0.5 pt min.	0.5 pt.
Box and Barlines	>0.5 pt min.	0.5 pt.
Character Per Inch	Not more than 35	35

*Headings are to be at least 10pt larger than body text.
 *The font size for the larger than other text used in DPP is 10pt. Requirements: 10pt min.

Drug Facts
Active ingredient (in each caplet)
 Naproxen sodium 220 mg (NSAID)
 naproxen 220 mg (NSAID)¹
 Pain reliever/fever reducer

Purposes
 Pain reliever/fever reducer

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

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
 • are age 65 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

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

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).

Questions or comments?
 1-800-395-0889 (Mon-Fri 9AM - 5PM EST)
 www.aleve.com

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

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

STRENGTH TO LAST 12 HOURS

ACTUAL SIZE

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

STRENGTH TO LAST 12 HOURS

ACTUAL SIZE

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

STRENGTH TO LAST 12 HOURS

ACTUAL SIZE

60
 CAPLET POUCHES
 CAPULET SHAPED TABLETS

Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981
 MADE IN MEXICO

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 000000000 Bayer



Actual Size 100%

FDA45095-2

CATEGORY	REQUIREMENT	ACTUAL IN FILE
Drug Facts Title	>8 pt.	8.1 pt.
Drug Facts Content	8 pt.	8 pt.
Headings*	8 pt bold italic	8 pt.
Subheadings	>8 pt.	8 pt.
Body Text	>8 pt.	8 pt.
Bullets	10 pt.	10 pt.
Linking	>8.5 pt.	8.5 pt.
Header lines	0.5 pt min.	0.5 pt.
Box and Barlines	>0.5 pt min.	0.5 pt.
Character Per Inch	Not more than 35	35

*Headings are to be at least 10pt larger than body text.
 *The font size for the larger than other text used in DPP is 10pt. Requirements: 10pt min.



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.
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 a other type size used in DPP
 † 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.
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%

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	≥5 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 DFP.
 † 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.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

* Headings are to be at least 20% larger than Body Text.
 ** Drug Facts Title to be larger than a 1 other type size used in DPP.
 † FDA recommends 2.5pt. rule.



Actual Size 100%

FDA45150-2

DRUG FACTS INFO	REQUIRED	ACTUAL IN FILE
Category		
Drug Facts Title	>8 pt**	9 pt
Drug Facts Continued	8 pt	8 pt
Headings ^{††}	8 pt bold italic ^{††}	8 pt
Subheadings	>8 pt	8 pt
Body Text	>8 pt	8 pt
Bullets	5 pt	12 pt
Leading	>0.5 pt	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 24pt larger than Body Text.
^{†††} Drug Facts Title to be larger than all other type size used in ODP.
^{††††} FDA recommends 2-3pt rule.

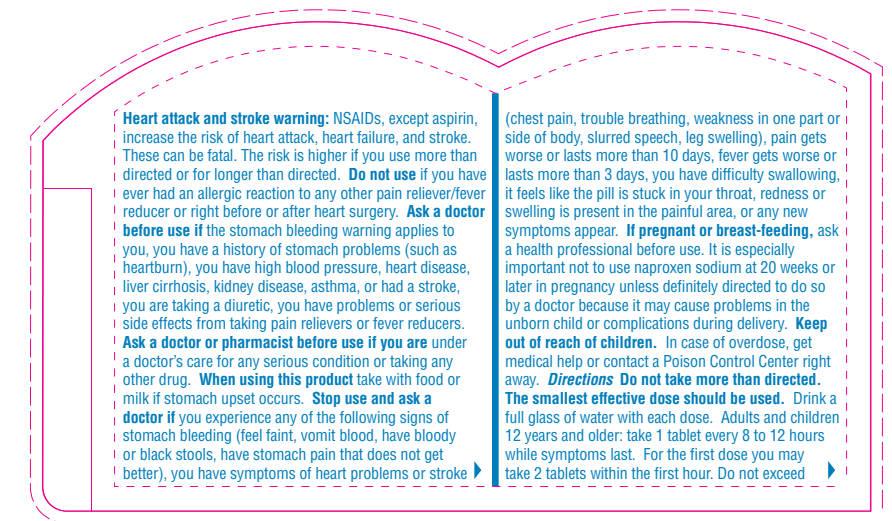
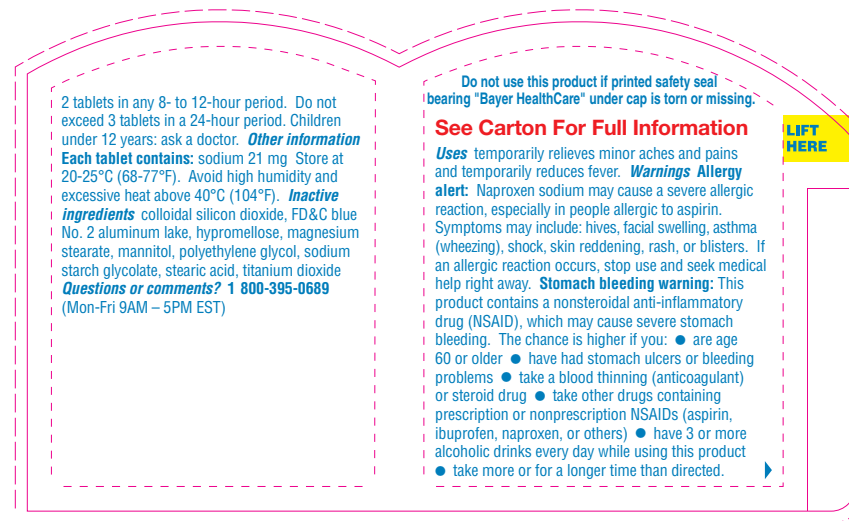
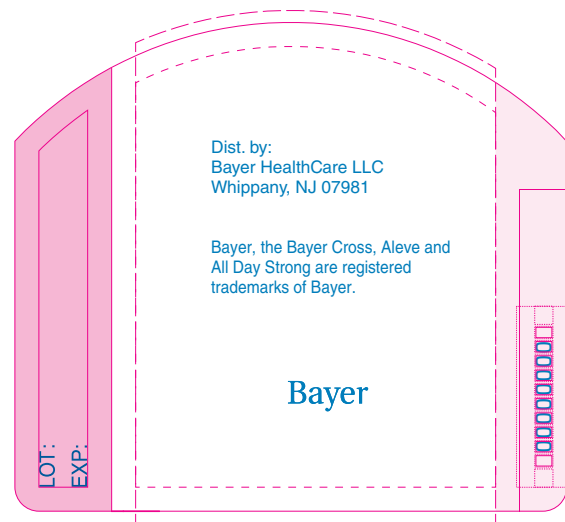


200%



Actual Size 100%

FDA00277-3



Actual Size 100%

FDA45152-5

DRUG FACTS INFO: (Modified Format -- updated 5/1/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt-bold italic*	6 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 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 2xts larger than Body Text
 ** Drug Facts Title to be larger than all other type size used in DFP
 † Box Bar line may be omitted and color contrast used to highlight Drug Facts Info



Actual Size 100%

FDA45154-2

DRUG FACTS INFO	REQUIRED	ACTUAL IN FILE
Category		
Drug Facts Title	>8 pt**	9 pt
Drug Facts Continued	8 pt	8 pt
Headings ^{††}	8 pt bold italic ^{††}	8 pt
Subheadings	>8 pt	8 pt
Body Text	>8 pt	8 pt
Bullets	5 pt	12 pt
Leading	>0.5 pt	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 24pt larger than Body Text.
^{†††} Drug Facts Title to be larger than all other type size used in ODP.
^{††††} FDA recommends 2-3pt rule.

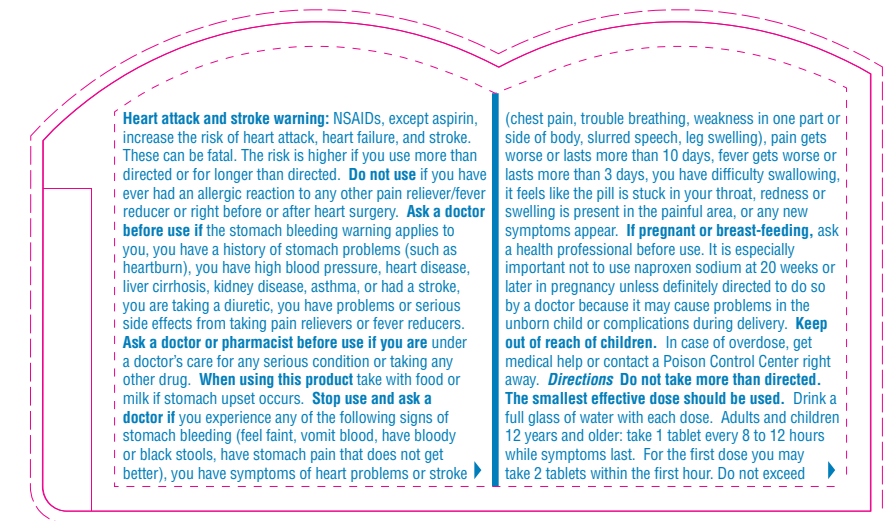
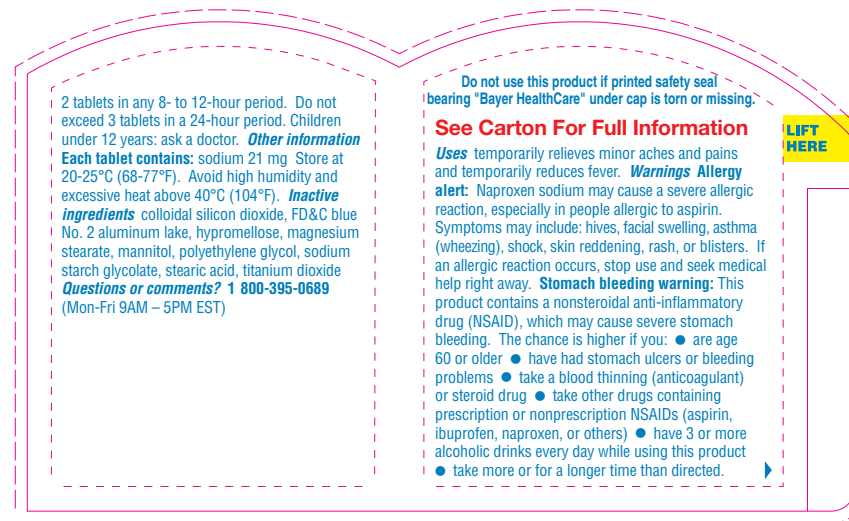
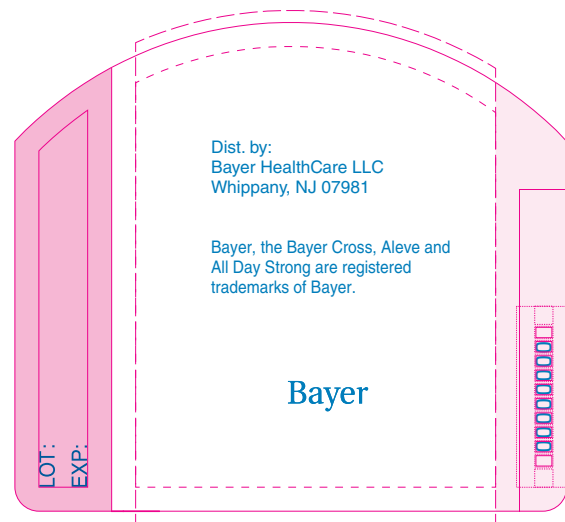


200%



Actual Size 100%

FDA00299-1



Actual Size 100%

FDA45152-5

DRUG FACTS INFO: (Modified Format -- updated 5/1/18)		
CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	>7.0 pt	-
Drug Facts Continued	7 pt	-
Headings*	7 pt-bold italic*	6 pt
Subheadings	≥6 pt	6 pt
Body Text	≥6 pt	6 pt
Bullets	5 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 2xts larger than Body Text
 ** Drug Facts Title to be larger than all other type size used in DFP
 † Box Bar line may be omitted and color contrast used to highlight Drug Facts Info

All Day Strong®



<p>Drug Facts</p> <p>Active ingredient (in each tablet) Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)* Pain reliever/fever reducer *nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> headache minor pain of arthritis backache toothache temporarily reduces fever muscular aches menstrual cramps the common cold <p>Warnings</p> <p>Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> hives asthma (wheezing) skin reddening facial swelling shock rash blisters <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> are age 60 or older have had stomach ulcers or bleeding problems take a blood thinning (anticoagulant) or steroid drug take other drugs containing prescription or nonprescription NSAIDs (aspirin, bupropfen, naproxen, or others) have 3 or more alcoholic drinks every day while using this product take more or for a longer time than directed <p>Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.</p>	<p>Purposes</p>	<p>Drug Facts (continued)</p> <p>Do not use</p> <ul style="list-style-type: none"> if you have ever had an allergic reaction to any other pain reliever/fever reducer right before or after heart surgery <p>Ask a doctor before use if</p> <ul style="list-style-type: none"> the stomach bleeding warning applies to you you have a history of stomach problems, such as heartburn you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke you are taking a diuretic you have problems or serious side effects from taking pain relievers or fever reducers <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> under a doctor's care for any serious condition taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin taking any other drug <p>When using this product</p> <ul style="list-style-type: none"> take with food or milk if stomach upset occurs <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you experience any of the following signs of stomach bleeding: <ul style="list-style-type: none"> feel faint have bloody or black stools have stomach pain that does not get better you have symptoms of heart problems or stroke: <ul style="list-style-type: none"> chest pain weakness in one part or side of body slurred speech leg swelling pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days you have difficulty swallowing it feels like the pill is stuck in your throat redness or swelling is present in the painful area any new symptoms appear 	<p>Drug Facts (continued)</p> <p>if pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than directed the smallest effective dose should be used drink a full glass of water with each dose <p>Adults and children 12 years and older</p> <ul style="list-style-type: none"> take 1 tablet every 8 to 12 hours while symptoms last for the first dose you may take 2 tablets within the first hour do not exceed 2 tablets in any 8- to 12-hour period do not exceed 3 tablets in a 24-hour period <p>Children under 12 years</p> <ul style="list-style-type: none"> ask a doctor <p>Other information</p> <ul style="list-style-type: none"> each tablet contains: sodium 21 mg store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). <p>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</p> <p>Questions or comments? 1-800-395-0689 (Mon - Fri 9AM - 5PM EST)</p> <p>DO NOT USE IF POUCH IS TORN OR OPEN.</p> <p>Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer. Dist. by: Bayer HealthCare LLC, Whippany, NJ 07981 ©2020 Bayer 00000000 Bayer</p>
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Actual Size 100%

FDA44943-4

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.	0.5 - 0.7 pt.
Hairlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch:	No more than 39	≤39

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



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%

X |

Do not use if pouch is torn or open.

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 you have a history of stomach bleeding warning applies to you you have a history of stomach problems, such as heartburn you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke you are taking a diuretic you have problems or serious side effects from taking pain relievers or fever reducers Ask a doctor or pharmacist before use if you are under a doctor's care for any serious condition taking aspirin for heart attack or stroke, because naproxen may decrease the benefit of aspirin taking any other drug. When using this product take with food or milk if stomach upset occurs. Stop use and ask a doctor if you experience any of the following signs of stomach bleeding (red, black, or dark stools, vomit blood, or black stools, have stomach pain that does not get better) you have symptoms of heart problems or stroke (chest pain, trouble breathing, weakness in one part or side of body, slurred speech, leg swelling) pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days you have difficulty swallowing it feels like the pill is stuck in your throat redness or swelling is present in the painful area any new symptoms appear If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions: Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 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: 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? 1-800-368-0899 (Mon-Fri 8AM - 8PM EST)
 Dist. by: Bayer HealthCare LLC MAJDE 38104
 Whippany, NJ 07981 0000000

Actual Size 100%

FDA45085-1.1

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	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%

FDA40321-2

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 ³	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.	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 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



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.
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%

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.
Headlines	0.5 pt. rule	0.5 pt.
Box and Barlines†	>0.5 pt. rule	2.5 pt.
Characters Per Inch	No more than 39	≤39

* Headings are to be at least 20% larger than Body Text.
 ** Drug Facts Title to be larger than a 1 other type size used in DPP.
 † 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. **	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.	6.8 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.
^{**} Drug facts title to be larger than all other type size used in DFP.
¹ FDA Recommends 2.5pt. rule.

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

/s/

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