



**Actual Size 100%**

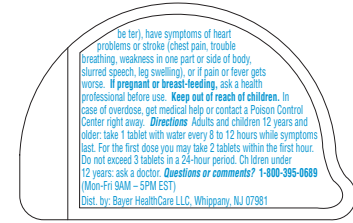
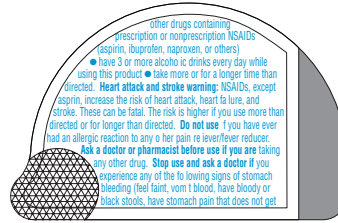
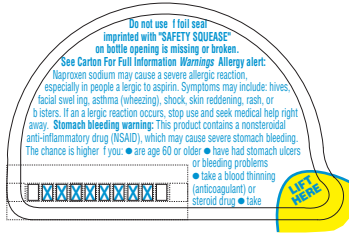
**MODIFIED DFL**

(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>7.0 pt	7.1 pt
Drug Facts	N/A	7 pt	7 pt
(continued):	N/A	7 pt	7 pt
Headings:	N/A	7 pt	7 pt
Subheadings:	N/A	6 pt	6 pt
Text:	N/A	6 pt	6 pt
Bullets:	N/A	5 pt (no larger)	5 pt
Leading:	N/A	+0.5 pt	6 pt
Characters Per Inch:	N/A	No more than 39	≤ 39

(b) (4)





**Actual Size 100%**

(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>8.0 pt	-
Drug Facts	N/A	8 pt	-
(continued):	N/A	8 pt	-
Headings:	N/A	8 pt	4.5 pt
Subheadings:	N/A	6 pt	4.5 pt
Text:	N/A	6 pt	4.5 pt
Bullets:	N/A	5 pt (no larger)	4 pt
Leading:	N/A	+0.5 pt	4.75 pt
Characters Per Inch:	N/A	No more than 39	>39

**Drug Facts**

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

**Uses**

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

**Warnings**

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

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

**Drug Facts (continued)**

- have 3 or more alcohol drinks every day while using this product
- take more or for a longer time than directed

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

**Do not use**

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

**Ask a doctor before use if**

- 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 any other drug

**When using this product:**

- take with food or a light meal; use as directed

**Stop use and ask a doctor if**

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

**Drug Facts (continued)**

**Questions or comments?** 1-800-395-0899 (Mon-Fri 9AM - 5PM EST)



3 25866 10503 5

**Do not use if carton is open or if foil seal is impunctured, with bottle opening, is missing, or broken.**

**SAFETY INFORMATION:**

Dist. by: Bayer Consumer Care LLC  
Bayer Consumer Care LLC  
Bayer, the Bayer Cross, Aleve and All Day Strong are registered trademarks of Bayer.  
Lot  
Exp

**Bayer**  
Made in



XXXXXXX

**Drug Facts (continued)**

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy, unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

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

**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 with the first hour
- do not exceed 2 tablets in any 8- to 12-hour period
- do not exceed 3 tablets in a 24-hour period

Children under 12 years: ask a doctor

**Other information**

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

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



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ALL DAY STRONG®

# ALEVE®

**BACK & MUSCLE PAIN**

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

for temporary relief of minor back and muscle aches and pains

**STRENGTH TO LAST 12 HOURS** **50 TABLETS**

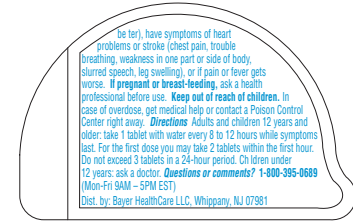
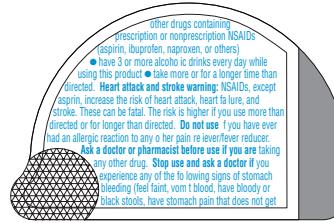
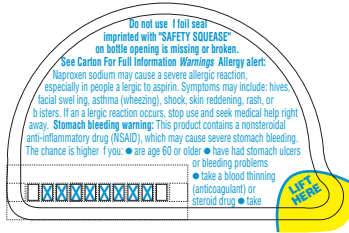
**Actual Size 100%**

(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>8.0 pt	8.1 pt
Drug Facts	N/A	8 pt	8 pt
(continued):	N/A	8 pt	8 pt
Headings:	N/A	8 pt	8 pt
Subheadings:	N/A	6 pt	6 pt
Text:	N/A	6 pt	6 pt
Bullets:	N/A	5 pt (no larger)	5 pt
Leading:	N/A	+0.5 pt	6-6.5 pt
Characters Per Inch:	N/A	No more than 39	≤ 39

(b) (4)





**Actual Size 100%**

(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>8.0 pt	-
Drug Facts	N/A	8 pt	-
(continued):	N/A	8 pt	-
Headings:	N/A	8 pt	4.5 pt
Subheadings:	N/A	6 pt	4.5 pt
Text:	N/A	6 pt	4.5 pt
Bullets:	N/A	5 pt (no larger)	4 pt
Leading:	N/A	+0.5 pt	4.75 pt
Characters Per Inch:	N/A	No more than 39	>39

ALL DAY STRONG®

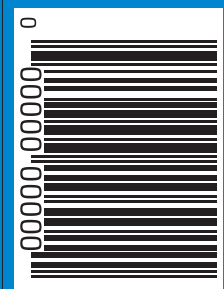
# ALEVE®

## BACK & MUSCLE PAIN

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

for temporary relief of minor back and muscle aches and pains

**STRENGTH TO LAST 12 HOURS**      **100 TABLETS**



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

**Drug Facts (continued)**

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These risks may be higher if you use 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 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

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

Dist. by: **Waters HealthCare LLC**  
 Whippany, NJ 07981

Lot \_\_\_\_\_  
 Exp \_\_\_\_\_

**Bayer**

Made in \_\_\_\_\_

**Drug Facts**

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

**Purposes**  
 \*nonsteroidal anti-inflammatory drug

**Uses**

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

**Warnings**

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

- hives
- skin redness
- asthma (wheezing)
- 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

**Drug Facts (continued)**

**if pregnant or breast-feeding, ask a health professional before use.** It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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

**Directions**

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

**Adults and children 12 years and older**

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

**Children under 12 years**

- ask a doctor

**Other information**

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

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

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

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**Actual Size 100%**

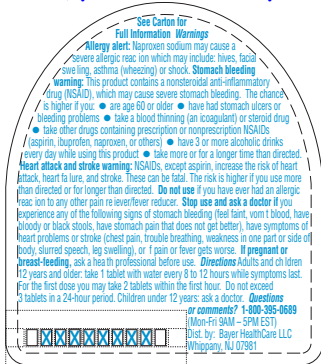
(b) (4)

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Drug Facts Title:	N/A	>8.0 pt	8.1 pt
Drug Facts (continued):	N/A	8 pt	8 pt
Headings:	N/A	8 pt	8 pt
Subheadings:	N/A	6 pt	6 pt
Text:	N/A	6 pt	6 pt
Bullets:	N/A	5 pt (no larger)	5 pt
Leading:	N/A	+0.5 pt	6.5-6.9 pt
Characters Per Inch:	N/A	No more than 39	≤ 39

(b) (4)



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



**Actual Size 100%**

(b) (4)

CATEGORY	PRIMARY PACKAGING REQUIRED	SECONDARY PACKAGING REQUIRED	ACTUAL SIZE IN FILE
Drug Facts Title:	N/A	>8.0 pt	-
Drug Facts	N/A	8 pt	-
(continued):	N/A	8 pt	-
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Subheadings:	N/A	6 pt	4.5 pt
Text:	N/A	6 pt	4.5 pt
Bullets:	N/A	5 pt (no larger)	4.5 pt
Leading:	N/A	+0.5 pt	5.0 pt
Characters Per Inch:	N/A	No more than 39	>39

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/  
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KAREN M MAHONEY  
08/22/2017