

**ALEVE CAPLETS- naproxen sodium tablet**  
**Your Safety Company**

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**Aleve®**  
**Caplets**

***Drug Facts***

**Active ingredient (in each caplet)**

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)<sup>1</sup>

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<sup>1</sup> nonsteroidal anti-inflammatory drug

**Purposes**

Pain reliever/fever reducer

**Uses**

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

**Warnings**

**Allergy alert**

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

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

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

**Stomach bleeding warning**

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

- are age 60 or older
- have had stomach ulcers or bleeding problems

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

**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, or kidney disease
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma

**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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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

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

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

**Directions**

- **do not take more than directed**
  - **the smallest effective dose should be used**
  - drink a full glass of water with each dose
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Adults and children 12 years and older	<ul style="list-style-type: none"><li>• take 1 caplet every 8 to 12 hours while symptoms last</li><li>• for the first dose you may take 2 caplets within the first hour</li><li>• do not exceed 2 caplets in any 8- to 12-hour period</li><li>• do not exceed 3 caplets in a 24-hour period</li></ul>
Children under 12 years	<ul style="list-style-type: none"><li>• ask a doctor</li></ul>

### Other information

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

### Inactive ingredients

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

### Questions or comments?

1-800-395-0689 (Mon - Fri 9AM - 5PM EST) or [www.aleve.com](http://www.aleve.com)

### PRINCIPAL DISPLAY PANEL - 50 Pouch Box

**ALL DAY STRONG**®

**ALEVE**®

*naproxen sodium tablets, 220 mg (NSAID)*

*Pain reliever/fever reducer*

**STRENGTH TO LAST 12 HOURS**

**CAPLETS**

**CAPSULE-SHAPED TABLETS**

ALL DAY STRONG®  
**ALEVE**®

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



**STRENGTH TO LAST 12 HOURS**

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



**STRENGTH TO LAST 12 HOURS**

**CAPLETS**  
CAPSULE-SHAPED TABLETS

Lot  
Exp

This Product is repackaged by Your Safety Company Inc,  
111 Quarry Road Chambersburg PA.17202, 800-548-3920  
(Mon-Fri 8:00am-5:00pm EST) from a product manufactured  
by Bayer. Bayer, the Bayer Cross, Aleve and All Day Strong  
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Bayer HealthCare LLC Whippany, NJ 07981

ALL DAY STRONG®  
**ALEVE**®



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



**STRENGTH TO LAST 12 HOURS**

**CAPLETS**  
CAPSULE-SHAPED TABLETS

**Drug Facts**

**Active ingredients (in each caplet)**

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

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

**Warnings**

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

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: • are age 50 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

**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 problems, or kidney disease • you are taking a diuretic • you have problems or serious side effects from taking pain relievers or fever reducers • you have asthma

**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 • the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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

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

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

**Directions** • do not use 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"> <li>• Take 1 caplet every 6 to 12 hours while symptoms last</li> <li>• for the first dose you may take 2 caplets within the first hour</li> <li>• do not exceed 2 caplets in any 8 to 12 hour period</li> <li>• do not exceed 3 caplets in a 24 hour period</li> </ul>
Children under 12 years	• ask a doctor

**Other information** • each caplet contains: sodium 20mg • 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, propylene glycol, polydioxane, talc, titanium dioxide

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

ALL DAY STRONG®

**ALEVE**

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



**STRENGTH TO LAST 12 HOURS**

**CAPLETS**  
CAPSULE-SHAPED TABLETS

Use Only If Pouch Is Sealed

50 Pouches of 1 Caplet Each

# ALEVE CAPLETS

naproxen sodium tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70262-301(NDC:0280-6000)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL (capsule shaped tablets)	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	Aleve
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70262-301-50	50 in 1 BOX		
1		1 in 1 POUCH; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
NDA	NDA020204	03/15/2016	

**Labeler** - Your Safety Company (050622331)

## Establishment

Name	Address	ID/FEI	Business Operations
Your Safety Company		050622331	RELABEL(70262-301)

Revised: 3/2016

Your Safety Company