

**ALEVE- naproxen sodium tablet tablet**  
**Lil' Drug Store Products, Inc**

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**Aleve**

***Drug Facts***

**Active ingredient (in each caplet)**

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

<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 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 informatin***

**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)

Dist. by: Bayer Healthcare LLC

Whippany, NJ 07981

**MADE IN MEXICO**

## **Principal Display Panel**

**WHILE FOLDED ON LINE, TEAR OPEN AT DOT OR USE SCISSORS**

**DO NOT USE IF POUCH IS TORN OR OPEN**

**ALL DAY STRONG®**

**ALEVE**

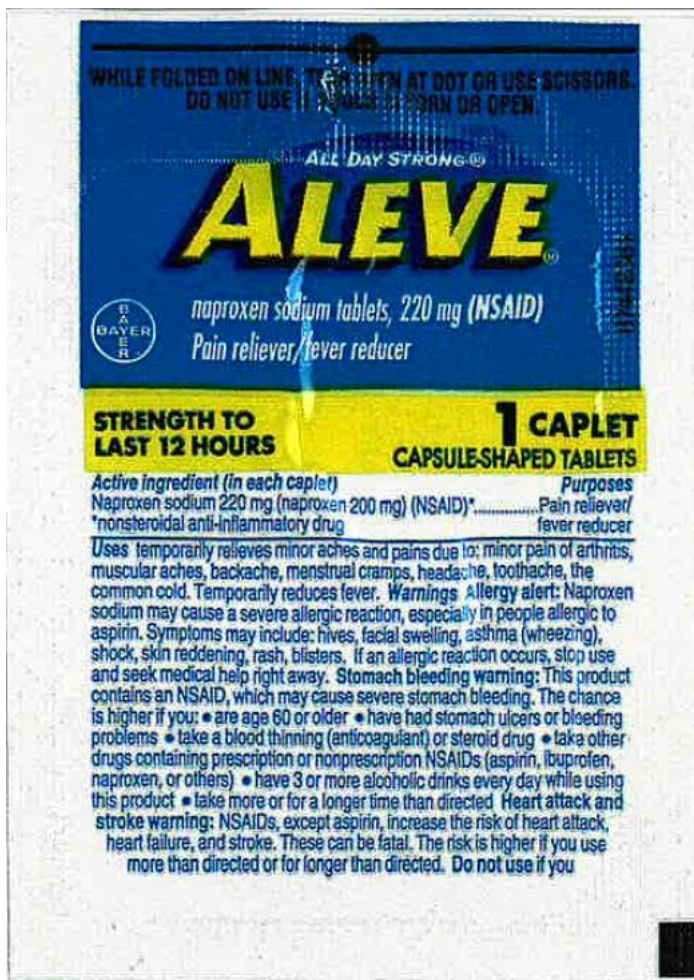
naproxen sodium tablets, 220 mg (**NSAID**)

Pain reliever/fever reducer

**STRENGTH TO LAST 12 HOURS**

**1 CAPLET**

**CAPSULE-SHAPED TABLETS**



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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 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. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Directions Do not take more than directed. The smallest effective dose should be used. Drink a full glass of water with each dose. Adults and children 12 years and older: take 1 caplet every 8 to 12 hours while symptoms last. For the first dose you may take 2 caplets within the first hour. Do not exceed 2 caplets in any 8- to 12-hour period. Do not exceed 3 caplets in a 24-hour period. Children under 12 years: ask a doctor. Other information Each caplet contains: sodium 20 mg. Store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F). Inactive ingredients FD&C blue #2 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide. Questions or comments? 1-800-395-0689 (Mon-Fri 9AM - 5PM EST)

Dist. by: Bayer HealthCare LLC  
Whippany, NJ 07881

MADE IN MEXICO  
88384784

NANDA NC E XP 6/1/2005

## ALEVE

naproxen sodium tablet tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-5103
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3W0)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<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:66715-5103-0	30 in 1 BOX, UNIT-DOSE	11/16/2006	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	11/16/2006	

**Labeler** - Lil' Drug Store Products, Inc (093103646)

Revised: 12/2022

Lil' Drug Store Products, Inc