

**ALEVE- naproxen sodium tablet**  
**R J General Corporation**

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**Aleve** ®

**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

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

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) or [www.aleve.com](http://www.aleve.com)

### Made in India

**PRINCIPAL DISPLAY PANEL - 50 Tablet Pouch Carton**

**ALL DAY STRONG®**

**ALEVE®**

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

**STRENGTH TO LAST 12 HOURS**

# 1 CAPLET CAPSULE-SHAPED TABLET



## ALEVE naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70264-011(NDC:0280-6000)
<b>Route of Administration</b>	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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MANNITOL (UNII: 3OWL53L36A)	

## Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	Aleve
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70264-011-01	50 in 1 CARTON	02/26/2014	
1		1 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	02/26/2014	

**Labeler** - R J General Corporation (122542830)

## Establishment

Name	Address	ID/FEI	Business Operations
R J General Corporation		122542830	repack(70264-011)

Revised: 11/2024

R J General Corporation