

ALEVE- naproxen sodium tablet
R J General Corporation

Aleve®

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)¹

¹ 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

-
- take 1 caplet every 8 to 12 hours while symptoms last

Adults and children 12 years and older	<ul style="list-style-type: none">• 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

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

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

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STRENGTH TO LAST 12 HOURS

1 CAPLET
CAPSULE-SHAPED TABLET

50 POUCHES OF 1 CAPLET



This product is repackaged by RJ General Corp, 2350 Burnet Ave., Cincinnati, Ohio 45219
 (513)621-3738 (Mon-Fri 9AM-3PM EST) from a product manufactured by Bayer.
 All Day Strong® and Aleve® are registered trademarks of Bayer, used with permission.

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 Nonsteroidal anti-inflammatory drug
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 • minor pain of arthritis • muscular aches • backache • menstrual cramps
 • headache • toothache • the common cold • temporarily reduces fever

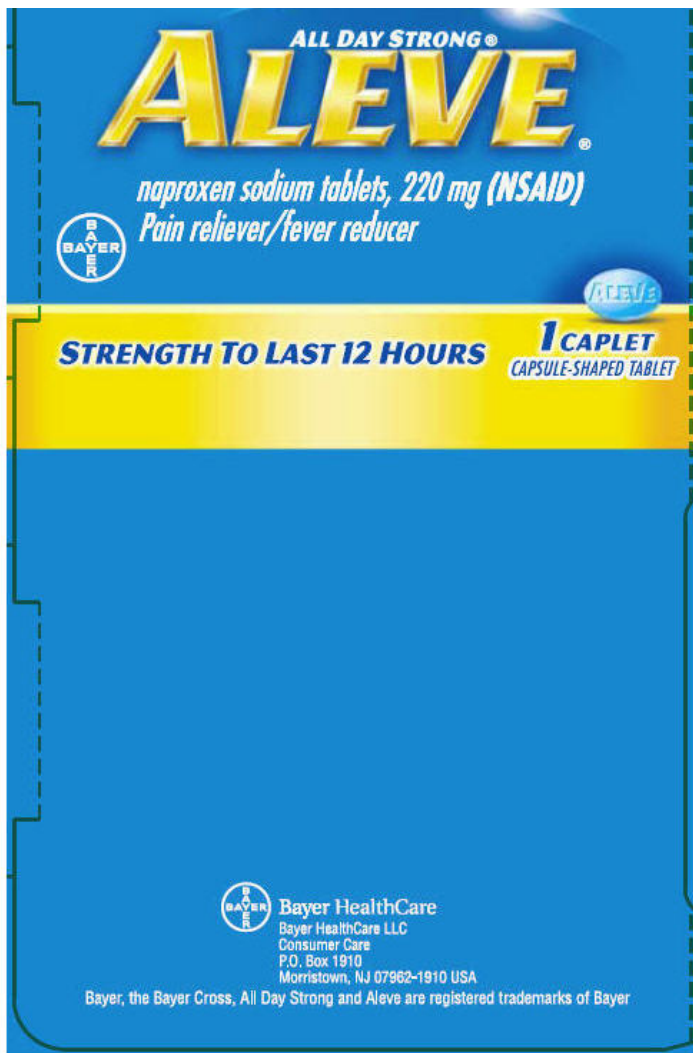
Warnings
Allergy alert: Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: • hives • facial swelling • asthma (wheezing) • shock • skin reddening • rash • blisters.
Stomach bleeding warning: This product contains an NSAID, which may cause 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 drug (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.
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, 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:
 • heart 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
 Adults and children 12 years and older • take 1 caplet every 8 to 12 hours while symptoms last and • do not exceed 2 caplets in any 8- to 12-hour period
 Children • ask a doctor under 12 years
 • do not exceed 3 caplets in a 24-hour period
 • 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
Other information • store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
 • each caplet contains: sodium 20 mg

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

Questions or comments?
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This dispenser contains tamper evident packets. Do not use if seal on individual packet is broken.



ALEVE

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70264-011(NDC:0280-6000)
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
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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: 7/2018

R J General Corporation