

NAPROXEN SODIUM- naproxen sodium capsule, liquid filled
AmerisourceBergen (Good Neighbor Pharmacy) 46122

Drug Facts

Active ingredient (in each capsule)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)*

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

Heart attack and stroke: 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 milk if stomach upset occurs

Stop use and ask a doctor if

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

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.(1-800-222-1222).

Directions

- **do not take more than directed**

- **the smallest effective dose should be used**
- drink a full glass of water with each dose
- if taken with food, this product may take longer to work
- adults and children 12 years and older:
 - take 1 capsule every 8 to 12 hours while symptoms last
 - for the first dose you may take 2 capsules within the first hour
 - do not exceed 2 capsules in any 8- to 12-hour period
 - do not exceed 3 capsules in a 24-hour period
- children under 12 years: ask a doctor

Other information

- **each capsule contains:** sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).
- read all directions and warnings before use. Keep carton.
- swallow whole; do not crush, chew, or dissolve

Inactive ingredients

FD&C blue #1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitan, sorbitol solution, titanium dioxide, white ink

Questions or comments?

Call **1-877-753-3935 Monday-Friday 9AM-5PM EST**

Principal Display Panel

[†]Compare to Aleve® active ingredient

Naproxen Sodium

Capsules, 220 mg

Pain Reliever; Fever Reducer (NSAID)

CAPSULES**

Liquid-Filled Capsules

[†]This product is not manufactured or distributed by Bayer HealthCare, LLC distributor of Aleve®.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed By AmerisourceBergen

1300 Morris Drive, Chesterbrook, PA 19087

www.mygnp.com

Product Label

Product of:

Lat / Exp.:

P.D.-CS28A F0004882



ABC#10185960

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(in each capsule)
Naproxen sodium 220 mg
(naproxen 200 mg) (NSAID)*

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temporarily relieves minor aches and pains due to:
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toothache
menstrual cramps
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
skin reddening
rash
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skin peeling
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Drug Facts (continued)

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:
vomit blood
have bloody or black stools
have stomach pain that does not get better
symptoms of heart problems or stroke:
slurred speech
leg swelling
weakness in one part or side of body
or lasts more than 10 days
fever gets worse or lasts more than 3 days
redness or swelling is present in the painful area
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Other information
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read all directions and warnings before use. Keep carton.
swallow whole; do not crush, chew, or dissolve

Inactive ingredients FD&C blue #1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbian solution, titanium dioxide, white ink

Questions or comments?
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Questions or Concerns? Visit us at www.mygrp.com

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*Compare to Aleve® active ingredient

NDC 46122-534-60

Naproxen Sodium

Capsules 220 mg

Pain Reliever/Fever Reducer (NSAID)

20 Liquid-Filled Capsules



GOOD NEIGHBOR PHARMACY Naproxen Sodium 220 mg

NAPROXEN SODIUM

naproxen sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46 122-534
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. 1 (UNII: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
LACTIC ACID (UNII: 33X04XA5AT)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITAN (UNII: 6O92ICV9RU)				
SORBITOL (UNII: 506T60A25R)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
ALCOHOL (UNII: 3K9958V90M)				
SHELLAC (UNII: 46N107B71O)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	BLUE	Score	no score	
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	PC19	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-534-60	1 in 1 BOX	04/01/2018	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA208363		04/01/2018	

Labeler - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)