

CAREALL NAPROXEN SODIUM- naproxen sodium tablet
New World Imports, Inc.

Active ingredients (in each caplet)

Active ingredient (in each caplet)

Naproxen sodium 220mg

(Naproxen 200mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever / fever reducer

Uses

Temporarily relieves minor aches and pains due to: minor pain of arthritis, backache, headache, muscular aches, menstrual cramps, toothache, and 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 NSAID, which may casue 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 everyday while using this product

take more or for a longer time than directed.

Heart attack and stroke warning: NSAIDs, except aspirin, increase the rist 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

Do not use:

If you have ever had an allergic reaction to any other pain reliever/fever reducer.

Right before or after heart surgery

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

When using this product**When using this product:**

Take with food or milk if stomach upset occurs.

Ask a Doctor**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 drugs

Stop use and ask a doctor**Stop use and ask a doctor if:**

You experience any of the following signs of stomach bleeding: you 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, or 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

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately (1-800-222-1222).

Directions

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 - 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 20mg

Inactive ingredients

croscarmellose sodium, FD&C blue 2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

NDC 51824-109-01

Drug Facts (continued)

- 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 croscarmellose sodium, FD&C blue #2, macroglol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

Questions or comments? 1-844-705-4384

CAREALL®

Naproxen Sodium Tablets, 220 mg

Strength to Last 12 Hours

- Pain Reliever
- Fever Reducer (NSAID)

†Compare to the active ingredient of Aleve®

100 CAPLETS™ **Capsule-shaped tablets

DO NOT USE IF IMPRINTED SEAL UNDER CAPLET IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet) Purpose
 Naproxen sodium 220 mg Pain reliever/
 (naproxen 200 mg) (NSAID)* 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
 - 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
- asthma (wheezing)
- facial swelling
- skin redness
- stomach pain
- 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

PEEL BACK HERE FOR MORE DRUG FACTS

Distributed by: CareAll Products
 160 Athens Way
 Nashville, TN 37228
www.careallproducts.com

0 85317-00608-2

This product is not manufactured or distributed by Bayer or Consumer Healthcare, LLC. (producer of Aleve® Caplets)

Drug Facts (continued)

- 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

Heart attack and stroke warning: 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
- 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 a 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
 - 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
 - weakness in one part or side of body
 - trouble breathing
 - 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.

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STOP PEELING

Hinge

CAREALL NAPROXEN SODIUM

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-109
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue	Score	no score
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Shape	OVAL	Size	12mm
Flavor		Imprint Code	17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-109-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/23/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	08/23/2024	

Labeler - New World Imports, Inc. (075372276)

Revised: 12/2025

New World Imports, Inc.