

CAREALL NAPROXEN- 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, 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 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 everyday 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

Do not use

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

Right before or after heart surgery

When using this product

When using this product:

Take with food or milk if stomach upset occurs.

Ask a Doctor

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 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 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

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

Inactive ingredients

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

Drug Facts (continued)

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
 - take 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, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

Questions or comments? 1-844-705-4384

NDC 51824-071-01

CAREALL
Naproxen
Sodium Tablets, 220 mg

All Day Pain Relief
Pain Reliever / Fever Reducer (NSAID)
8-12 Hour Relief

100 CAPLETS (Caplet-shaped tablets)

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
 - 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)
- skin redness
- shock
- 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: WIL, Inc.
100 Albemarle Way, Nashville, TN 37228
LT145193LL_R0

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This product is not manufactured or distributed by WIL, Inc. It is manufactured by WIL, Inc., a subsidiary of W.L. Alford, LLC, distributor of Allegra®.

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)
- take 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, including naproxen, may 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 such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are being or were on other 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
 - 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 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).

STOP PEELING

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CAREALL NAPROXEN

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-071
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
CROSCARMELOSE SODIUM (UNII: M28OL1HF48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-071-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	01/14/2019	

Labeler - New World Imports, Inc. (075372276)