

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

Do not use:

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

CAREALL NAPROXEN

naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-072
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: M28OL1HH48)	
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:51824-072-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	01/16/2019	

Labeler - New World Imports, Inc. (075372276)

