NAPROXEN SODIUM- naproxen sodium tablet
NuCare Pharmaceuticals,Inc.

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gc 951

Active ingredient (in each tablet)

Naproxen sodium 220 mg
(Naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/ fever reducer

Uses

temporarily relieves minor aches and pain due to:

- backache
- muscular aches
- minor pain of arthritis
- 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

- 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 doctor if

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have a stomach pain that dose 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

Adults and children 12 years and older:	• take 1 tablet every 8 to12 hours while symptoms last • for first dose you may take 2 tablets with in the first hour • do not exceed 2 tablets in any 8-to 12-hour period • do not exceed 3 tablets in a 24-hour period
Children under 12 years:	• ask a doctor

Storage

- Store at 20-25 ^{o}C (68-77 ^{o}F). Avoid high humidity and excessive heat above 40 ^{0}C (104 ^{0}F)

Other information

- **each tablet contains:** sodium 20 mg
- If side effects occur, you may report side effects to FDA at 1-800-FDA-1088

Inactive ingredients

Colloidal silicon dioxide, croscarmellose sodium, FD&C blue #2 lake, Hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide.

Questions or comments?

Call 1-800-540-3765

Principal Display Panel

NAPROXEN SODIUM
naproxen sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-3223(NDC:57896-951)
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	144
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-3223-1	21 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2018	
2	NDC:68071-3223-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/22/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	05/01/2012	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(68071-3223)

Revised: 3/2019 NuCare Pharmaceuticals,Inc.