NAPROXEN PAIN RELIEF- naproxen sodium tablet Rebel Distributors Corp

Naproxen Drug Facts

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 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
- 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 asthma

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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
- 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
- you develop heartburn
- 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)

Directions

- do not take more than directed
- the smallest effective dose should be used
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- drink a full glass of water with each dose

Adults and	• take 1 tablet every 8 to 12 hours while
children	symptoms last

12 years and older	 for the first dose you may take 2 tablets within 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

Other information

- each tablet contains: sodium 20 mg
- store at 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

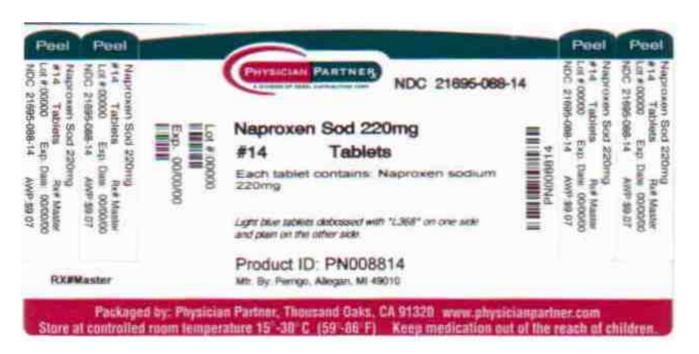
Inactive ingredients

FD&C blue no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel



NAPROXEN PAIN RELIEF naproxen sodium tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:21695-088(NDC:24385-490)

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength	
NAPRO XEN SO DIUM (UNII: 9TN87S3A3C) (NAPRO XEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989GH94E)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		

Product Characteristics			
Color	BLUE (Light Blue)	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	L490
Contains			

I	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:21695-088-14	14 in 1 BOTTLE			
2	NDC:21695-088-30	30 in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074661	03/12/1998	

Labeler - Rebel Distributors Corp (118802834)

Establishment				
Name	Address	ID/FEI	Business Operations	
Rebel Distributors Corp		118802834	RELABEL, REPACK	

Revised: 2/2011 Rebel Distributors Corp