GOOD SENSE ALL DAY PAIN RELIEF- naproxen sodium tablet, film coated Bryant Ranch Prepack

Naproxen Sodium

Active ingredient (in each caplet)

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 caplet every 8 to 12 hours while
children 12		symptoms last

years and older	 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

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

Naproxen Sodium 220mg Tablet

GOOD SENSE ALL DAY PAIN RELIEF

naproxen sodium tablet, film coated

Pro	duct	Information

Product Type

HUMAN PRESCRIPTION DRUG LABEL

Item Code (Source)

NDC:636291793(NDC:0113-0368)

Route of Administration ORAL DEA Schedule

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
NAPRO XEN SO DIUM (NAPRO XEN)	NAPROXEN SODIUM	220 mg	

Inactive Ingredients				
Ingredient Name Str				
FD&C BLUE NO. 2				
HYPROMELLOSES				
MAGNESIUM STEARATE				
CELLULO SE, MICRO CRYSTALLINE				
POLYETHYLENE GLYCOLS				
POVIDONES				
TALC				
TITANIUM DIO XIDE				

Product Characteristics			
Color	BLUE (Light Blue)	Score	no score
Shape	CAPSULE (oval)	Size	12mm
Flavor		Imprint Code	L368
Contains			

Packaging				
Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:63629-1793-2	20 in 1 BOTTLE			
NDC:63629-1793-3	30 in 1 BOTTLE			
NDC:63629-1793-4	40 in 1 BOTTLE			
NDC:63629-1793-5	50 in 1 BOTTLE			
NDC:63629-1793-6	60 in 1 BOTTLE			
NDC:63629-1793-7	14 in 1 BOTTLE			
NDC:63629-1793-8	100 in 1 BOTTLE			
		Item Code Package Description NDC:63629-1793-2 20 in 1 BOTTLE NDC:63629-1793-3 30 in 1 BOTTLE NDC:63629-1793-4 40 in 1 BOTTLE NDC:63629-1793-5 50 in 1 BOTTLE NDC:63629-1793-6 60 in 1 BOTTLE NDC:63629-1793-7 14 in 1 BOTTLE	Item Code Package Description Marketing Start Date NDC:63629-1793-2 20 in 1 BOTTLE NDC:63629-1793-3 30 in 1 BOTTLE NDC:63629-1793-4 40 in 1 BOTTLE NDC:63629-1793-5 50 in 1 BOTTLE NDC:63629-1793-6 60 in 1 BOTTLE NDC:63629-1793-7 14 in 1 BOTTLE	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	0 1/14/19 9 7	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment			
Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-1793), RELABEL(63629-1793)

Revised: 1/1997 Bryant Ranch Prepack