NAPROXEN SODIUM- naproxen sodium tablet, film coated, extended release
J.P. BUSINESS ENTERPRISE

ALL DAY PAIN RELIEF

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)[1]

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[1] nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
  - backache
  - headache
  - menstrual cramps
  - minor pain of arthritis
  - muscular aches
  - the common cold
  - toothache
- temporarily reduces fever

Warnings

Allergy alert

Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- asthma (wheezing)
- blisters
- facial swelling
- hives
- rash
- shock
- skin reddening

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning

This product contains a nonsteroidal anti-inflammatory drug (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 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
- 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**
- drink a full glass of water with each dose

	■ take 1 tablet every 8 to 12 hours while symptoms

Adults and Children 12 years and older:	last ■ 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 between 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F)

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?

1-888-333-9792

Distributed By: J.P Business Enterprise
Lake Grove, NY 11755

PRINCIPAL DISPLAY PANEL - 15 Tablet Bottle Carton

VALUMEDS

SEE NEW WARNINGS INFORMATION

Compare to the active ingredient
in **ALEVE**®*

ALL DAY
PAIN RELIEF

NAPROXEN SODIUM TABLETS, USP 220 mg

PAIN RELIEVER/FEVER REDUCER **(NSAID)**

- ***STRENGTH TO LAST 12 HOURS***

15 TABLETS (OVAL-SHAPED)

NAPROXEN SODIUM

naproxen sodium tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59105-003
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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONES (UNII: FZ989GH94E)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	144
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59105-003-15	1 in 1 CARTON		
1		15 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	08/20/2013	

Labeler - J.P. BUSINESS ENTERPRISE (078775890)

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