GOOD SENSE ALL DAY PAIN RELIEF- naproxen sodium tablet Dispensing Solutions, Inc.

Perrigo All Day Pain Relief 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 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

Adults and children 12 years and older	 take 1 tablet every 8 to 12 hours while symptoms 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 21 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

Strength to Last 12 Hours

See New Warnings Information

All Day Pain Relief

Naproxen Sodium Tablets, 220 mg

Pain Reliever & Fever Reducer (NSAID)

Actual Size

Compare to active ingredient of Aleve® Tablets

NDC 66336-0002-XX

NDC 66336-0002-40

BULK SOURCE DATA
DIST. BY: PERRIGO
ALLEGAN, MI 49010
PRODUCT ID:

PRODUCT ID: LIGHT BLUE ROUND TABLET IMPRINTED L490

BULK SOURCE NDC: 00113-9490-78

MFR. LOT: XXXXXX
PEDIGREE #: 17014648
DISPENSE IN THIS

TIGHT/LIGHT RESISTANT CONTAINER



TAKE ORALLY EVERY
HOURS TIMES A DAY.
AS NEEDED
TAKE WITH FOOD.
AVOID ALCOHOL.
MAY CAUSE DIZZINESS.



NAPROXEN SODIUM 220 mg

XX TABLETS NDC 66336-0002-XX PRODUCT # 292-XX

EACH TABLET CONTAINS: NAPROXEN SODIUM 220 mg (NAPROXEN 200 mg) (PURPOSES: PAIN RELIEVER / FEVER REDUCER) "STOMACH BLEEDING WARNING: THIS PRODUCT CONTAINS A NONSTERO!DAL ANT-INFLAMMATORY DRUG (NSAID), WHICH MAY CAUSE 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 AN NSAID (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 DIRECTEO."

COMPARE TO ACTIVE INGREDIENT OF ALEVE TABLETS

LOT# SAMPLE EXP: 00-00 Rx # 22033399

WARNING: KEEP OUT OF CHILDREN'S REACH STORE AT 68°- 77° F. SEE USP.

292- XX NDC 66336-0002- XX NAPROXEN SOO!UM 220 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00113-9490-78 RX# 22033399

292- XX NDC 66336-0002- XX NAPROXEN SODIUM 220 mg XX TABLETS LOT # SAMPLE EXP: 00-00 MN 00113-9490-78 RX# 22033399

292- XX NDC 66336-0002- XX NAPROXEN SODIUM 220 mg XX TABLETS EXP: 00-00 MN 00113-9490-78 RX# 22033399





GOOD SENSE ALL DAY PAIN RELIEF

Rev. Date: 08/10

naproxen sodium tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:66336-002(NDC:0113-9490)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthNAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)NAPROXEN SODIUM220 mg

Inactive Ingredients				
Ingredient Name	Strength			
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
PO VIDO NES (UNII: FZ989 GH9 4E)				
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				

Packaging						
#	Item Code	Package Description	Marketin	g Start Date	Ma	arketing End Date
1	NDC:66336-002-40	40 in 1 BOTTLE				
Marketing Information						
Mai Keting initi mation						
M	larketing Category A	pplication Number or Monogra	ph Citation	Marketing Start	Date	Marketing End Date
Αľ	NDA AN	DA074661		0 1/14/19 9 7		

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment						
Name	Address	ID/FEI	Business Operations			
Dispensing Solutions, Inc.		066070785	relabel(66336-002), repack(66336-002)			

Revised: 7/2013 Dispensing Solutions, Inc.