NAPROXEN SODIUM- naproxen sodium tablet Northwind Pharmaceuticals, LLC

Naproxen Sodium 220 MG

Indications and Usage

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

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
- •vou are taking a diuretic
- •you have problems or serious side effects from taking pain relievers or fever reducers
- •vou 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)

Dosage

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

Label

NDC: 51655-624-24 MFG: 45802-490-78

Naproxen Sodium 220 MG

24 Tablets

OTC

Lot#

Exp. Date:

Each tablet contains naproxen sodium....220 mg

Sodium....21 mg

Dosage: See prescribing information.

Store at 68 to 77 degrees F

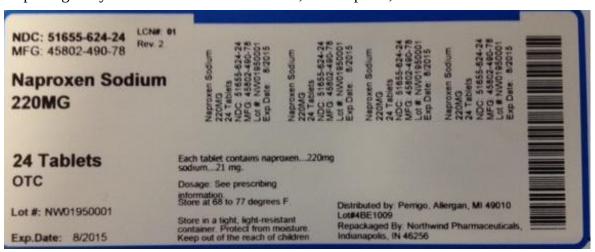
Store in a tight, light-resistant container. Protect from moisture.

Keep out of the reach of children.

Distributed by: Perrigo, Allergan, MI 49010

Lot#

Repackaged by Northwind Pharmaceuticals, Indianapolis, IN 46256



NAPROXEN SODIUM

naproxen sodium tablet

Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:51655-624(NDC:45802-490) Route of Administration ORAL

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

Product Characteristics			
Color	blue	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	L490
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51655-624-24	24 in 1 BOTTLE, DISPENSING		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074661	07/14/2014	

Labeler - Northwind Pharmaceuticals, LLC (036986393)

$\pmb{Registrant - \text{Northwind Pharmaceuticals, LLC } (036986393)}$

Establishment			
Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals, LLC		036986393	repack(51655-624)

Revised: 7/2014 Northwind Pharmaceuticals, LLC