

**NAPROXEN SODIUM- naproxen sodium tablet**  
**Northwind Pharmaceuticals, LLC**

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**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
- 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)

## **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

**NDC: 51655-624-24** LCN# 01  
**MFG: 45802-490-78** Rev. 2

**Naproxen Sodium**  
**220MG**

**24 Tablets**  
**OTC**

Lot #: NW01950001  
Exp. Date: 8/2015

Each tablet contains naproxen...220mg  
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#4BE1009  
Repackaged By: Northwind Pharmaceuticals,  
Indianapolis, IN 46256

## NAPROXEN SODIUM

naproxen sodium tablet

## Product Information

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

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN	220 mg

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	L490
<b>Contains</b>			

## Packaging

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

## Marketing Information

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

**Labeler** - Northwind Pharmaceuticals, LLC (036986393)

**Registrant** - Northwind Pharmaceuticals, LLC (036986393)

## Establishment

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

Revised: 7/2014

Northwind Pharmaceuticals, LLC