

NAPROXEN SODIUM- naproxen sodium capsule, liquid filled
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd

Naproxen Sodium Capsules 220 mg

Drug Facts

Active ingredient (in each capsule)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

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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

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

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

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
 - you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear
- you have difficulty swallowing
- it feels like the capsule is stuck in your throat

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.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- drink a full glass of water with each dose
- if taken with food, this product may take longer to work

adults and children 12 years and older:	<ul style="list-style-type: none">• take 1 capsule every 8 to 12 hours while symptoms last• for the first dose you may take 2 capsules within the first hour• do not exceed 2 capsules in any 8- to 12-hour period• do not exceed 3 capsules in a 24-hour period
children under 12 years:	<ul style="list-style-type: none">• ask a doctor

Other information

- **each capsule contains:** sodium 20 mg
- store at 20-25°C (68-77°F) avoid high humidity and excessive heat above 40°C (104°F)
- read all directions and warnings before use. Keep carton.

Inactive ingredients

FD&C blue#1, gelatin, glycerin, lactic acid, lecithin, light mineral oil, n-butyl alcohol, polyethylene glycol, povidone, propylene glycol, purified water, shellac glaze, sorbitol sorbitan solution, titanium dioxide, white ink

Questions or comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL - Shipping Label

Naproxen Sodium 220 mg Bulk

NDC: 53345-042-01

Each softgel contains: Naproxen Sodium 220 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Quantity: 5,000 Capsules

MADE IN CHINA

IMPORTANT:

1. Inspect immediately upon receipt.
2. This is a bulk shipment, intended for further processing only.
3. Protect from heat, humidity, and light. Do not refrigerate.
4. Store at 20-25°C (68-77°F) and avoid excessive heat above 40°C (104°F).

Humanwell Puracap Pharmaceuticals (Wuhan)Co., Ltd

No. 99, 2nd Shendun Road, East Lake New Technology Development District,

Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-042-01

Product:

Naproxen Sodium Capsules 220 mg

Each softgel contains: Naproxen Sodium 220 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00018

Package Size:

5000 Capsules

Lot Number:

xxxxxxx

Manufacturing Date: mm/yyyy

Expiry Date: mm/yyyy

Box No.:

IMPORTANT:

1. Inspect immediately upon receipt.
2. This is a bulk shipment, intended for further processing only.
3. Protect from light. Do not refrigerate.
4. Store at 20-25°C (68-77°F) avoid high humidity and excessive heat above 40°C(104°F)

MADE IN CHINA

Humanwell PuraCap Pharmaceuticals (Wuhan) Co.,Ltd

NDC #: 53345-042-01

PLD Item: BK000437



NAPROXEN SODIUM 220MG SOFTGEL BULK

LOT # XXXXXXXX

MFG DATE: DD/MM/YY



QTY/Case: 5,000 capsules

CAUTION:
FOR FUTURE MANUFACTURING,
PROCESSING OR REPACKAGING

IMPORTANT:

1. Protect from heat, humidity, and light.
2. Store at 20-25°C (68-77°F) and avoid excessive heat above 40°C (104°F).

Made in China

COMMENTS:
PO#:

REV-01
03/2018

NAPROXEN SODIUM

naproxen sodium capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-042
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (CLEAR)	Score	no score
Shape	capsule (OBLONG)	Size	20 mm
Flavor		Imprint Code	PC19
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-042-01	1 in 1 BOX	03/20/2018	
1		5000 in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208363	03/20/2018	

Labeler - Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd (421293287)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(53345-042) , analysis(53345-042)

Revised: 11/2019

Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd