

NAPROXEN SODIUM- naproxen sodium tablet, film coated
PD-Rx Pharmaceuticals, Inc.

Naproxen Sodium Tablets 220 mg Drug Facts

Active ingredient (in each tablet)

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

*nonsteroidal anti-inflammatory drug

Purposes

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
- 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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

16 HOW SUPPLIED

Naproxen Sodium Tablets are available as follows:

220 mg: Light Blue, round, tablet, debossed "L490". Available in bottles of

20 tablets (NDC 43063-909-20)

30 tablets (NDC 43063-909-30)

Principal Display Panel

Naproxen Sodium Tablets 220 mg

Drug Facts		Drug Facts (continued)	Drug Facts (continued)
Active Ingredient (in each tablet) Naproxen Sodium 220 mg (naproxen 200 mg) (NSAID)* *nonsteroidal anti-inflammatory drug		Do not use • If you have ever had an allergic reaction to any other pain reliever/fever reducer • right before or after heart surgery	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
Purposes Pain reliever/ Fever Reducer		Ask a doctor or pharmacist before use if you are • taking any other drug	
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		When using this product • take with food or milk if stomach upset occurs	Children under 12 years • ask a doctor Questions or comments? 1-800-719-9260
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.		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 • slurred speech • leg swelling • weakness in one part or side of the body • 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	
Ask a doctor before use if you have • 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		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)	Marketed and Packaged by: PD-Rx Pharmaceuticals, Inc Oklahoma City, OK 73127 1-405-942-3040 V.8.19.10 GTIN: 00343063909300 SNO: C21E700001 EXP: 03/2023 LOT: C21E70
		Other information: • each tablet contains: sodium 21mg • 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	NDC 43063-909-30  NAPROXEN SODIUM 220 mg Pain Reliever/Fever Reducer (NSAID) Strength To Last 12 Hours  30 Tablets TAMPER EVIDENT: DO NOT USE IF SEAL IS BROKEN OR MISSING FROM BOTTLE.

NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC: 43063-909(NDC:45802-490)
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
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue (Light Blue)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	L490
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43063-909-20	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	
2	NDC:43063-909-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074661	04/11/2014	

Labeler - PD-Rx Pharmaceuticals, Inc. (156893695)

Registrant - PD-Rx Pharmaceuticals, Inc. (156893695)

Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack(43063-909)

Revised: 10/2023

PD-Rx Pharmaceuticals, Inc.