NAPROXEN- naproxen sodium tablet
Preferred Pharmaceuticals, Inc.

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gc 951-954L

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 pain due to:

- backache
- muscular aches
- minor pain of arthritis
- 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

- 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 doctor if

- you experience any of the following signs of stomach bleeding:
    - feel faint
    - vomit blood
    - have bloody or black stools
    - have a stomach pain that dose not get better
- you have symptoms of heart problems or stroke

 leg swelling chest pain

 slurred speech trouble breathing
 weakness in one part or side of 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

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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
- 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

Storage

- Store at 20-25 ^{o}C (68-77 ^{o}F). Avoid high humidity and excessive heat above 40 ^{0}C (104 ^{0}F)

Other information

- **each tablet contains:** sodium 20 mg
  NDC 68788-7582-02 Bottle of 20
  NDC 68788-7582-03 Bottle of 30
  NDC 68788-7582-04 Bottle of 40
  NDC 68788-7582-06 Bottle of 60

Repackaged by Preferred Pharmaceuticals, Inc.

Inactive ingredients

croscarmellose sodium, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

Questions or comments?

Call 1-800-540-3765

Principal Display Panel

NAPROXEN

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68788-7572(NDC:57896-954)
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	blue	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;417
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7572-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2019	
2	NDC:68788-7572-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2019	
3	NDC:68788-7572-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2019	
4	NDC:68788-7572-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204872	01/01/2019	

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Registrant - Preferred Pharmaceuticals, Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	REPACK(68788-7572)

Revised: 8/2023 Preferred Pharmaceuticals, Inc.