NAPROXEN SODIUM- naproxen sodium tablet, film coated
Safrel Pharmaceuticals, LLC.

Naproxen Sodium Tablets, USP 220 mg

ACTIVE INGREDIENT(S)

(in each tablet/caplet)

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

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USE(S)

• 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

• 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 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

PREGNANCY/BREASTFEEDING

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 20
weeks or later in 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

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 20 mg
- store at 20 - 25°C (68 - 77°F). Avoid high humidity and excessive heat above 40°C (104°F)

INACTIVE INGREDIENT

Inactive Ingredients FD&C blue#2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate,

stearic acid, titanium dioxide

Questions or Comments?

1-844-384-3723 Mon - Fri 9:00 AM to 4:30 PM EST

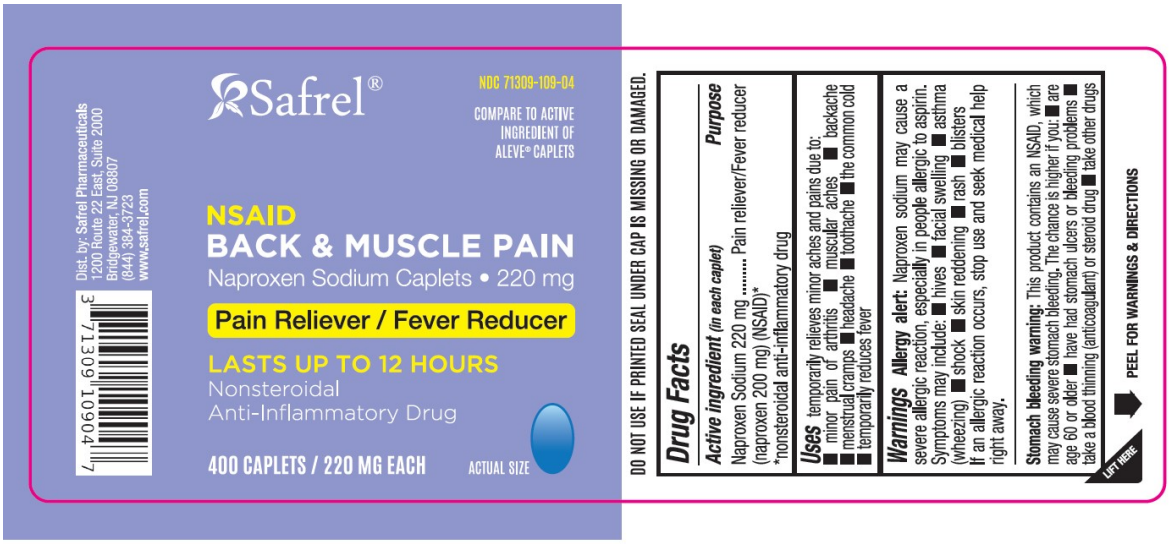
Do not use if carton is open or of foil seal on bottle opening is missing or broken.

Manufactured for:
Safrel Pharmaceuticals

Bridgewater, NJ 08807

www.safrel.com

PRINCIPAL DISPLAY PANEL



NAPROXEN SODIUM

naproxen sodium tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71309-109
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	blue (Light Blue)	**Score**	no score
Shape	OVAL (Caplet -Shaped)	**Size**	12mm
Flavor		**Imprint Code**	220
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71309-109-04	400 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	09/30/2021	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 12/2022 Safrel Pharmaceuticals, LLC.