NAPROXEN SODIUM- naproxen sodium tablet
A-S Medication Solutions

Naproxen Sodium Tablets, USP 220 mg (NSAID)**
Pain reliever/fever reducer
STRENGTH TO LAST 12 HOURS

Active ingredient (For Tablet)

(in each tablet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)**

**nonsteroidal anti-inflammatory drug

Active ingredient (For Caplet)

(in each caplet)

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

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 the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions (For Tablets)

■ **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

Directions (For Caplets)

■ **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 caplet every 8 to 12 hours while symptoms last

■ for the first dose you may take 2 caplets within the first hour

■ do not exceed 2 caplets in any 8- to 12- hour period

■ do not exceed 3 caplets in a 24- hour period

Children under 12 years

■ ask a doctor

Other information (For Tablet)

■ **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)

Other information (For Caplet)

■ **each caplet contains:** sodium 20 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 #2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or comments?

1-877-770-3183 Mon - Fri 9:00 AM to 4:00 PM EST.

HOW SUPPLIED

Product: 50090-5538

NDC: 50090-5538-1 10 TABLET in a BOTTLE

NAPROXEN SODIUM TABLET

NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-5538(NDC:69848-010)
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	blue	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-5538-1	10 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	07/01/2019	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-5538)

Revised: 5/2021 A-S Medication Solutions