NAPROXEN SODIUM- naproxen sodium tablet
Safeway, Inc

Pain Relief

Naproxen SodiumTablets, USP 220mg (NSAID)

Pain Reliever/ Fever Reducer

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

Strength to last 12 hours

Active ingredient (in each tablet)

Naproxen sodium 220 mg

(naproxen 200mg) (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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
■ 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 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 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.

n 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 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?

call **1-877-770-3183** Mon - Fri 8:00 AM EST to 5:00 PM PST

PDP


COATING
FREE AREA
700000003409
200000004485
Drug Facts (continued)
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DISTRIBUTED BY:
BETTER LIVING BRANDS LLC
P.O. BOX 99
FLEMINGTON, NJ 08822-0099
1-888-724-2626
MADE IN INDIA
Scan here for more information
Signature care.
Quality Guaranteed
Compare to Aleve* Tablets
active ingredient*
NDC 21130-061-09
Pain Relief
NAPROXEN SODIUM TABLETS, USP 220 mg
(NSAID)**
Pain Reliever/Fever Reducer
Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)
STRENGTH TO LAST 12 HOURS
Actual Size
90 TABLETS
*This product is not manufactured or distributed by Bayer HealthCare, LLC., distributor of Aleve. Aleve is a registered Trademark of Bayer HealthCare, LLC.
RD 23198
3 21130 18716 5
Lot
Exp.
COATING
FREE AREA
Important: Read all warnings and directions before use. Keep carton for important information.
DO NOT USE IF CARTON IS OPEN OR IF FOIL SEAL ON BOTTLE OPENING IS MISSING OR BROKEN
Drug Facts
Active ingredient (in each tablet) Purposes
Naproxen sodium 220 mg Pain reliever/fever reducer
(naproxen 200 mg) (NSAID)**
**nonsteroidal anti-inflammatory 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
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NAPROXEN SODIUM

naproxen sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21130-061
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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	blue (Light Blue)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	220
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-061-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2023	
2	NDC:21130-061-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	09/30/2023	

Labeler - Safeway, Inc (009137209)

Revised: 12/2023 Safeway, Inc