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:
- \blacksquare chest pain \blacksquare trouble breathing \blacksquare weakness in one part or side of body \blacksquare slurred speech \blacksquare 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

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Drug Facts (continued)

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(NSAID)**

Compare to Alleve* Tablets

Quality Guaranteed

Pain Relief

NAPROXEN SODIUM

TABLETS, USP 220 mg

Pain Reliever/Fever Reducer

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

STRENGTH TO LAST 12 HOURS

Important Read all warnings and directions before use.
Keep carton for important information.

OO NOT USE IF CARTON IS OPEN OR IF FOIL SEAL OH
BOTTLE OPENING IS MISSING OR BROKEN NDC 21130-061-09

Actual Size

Drug Facts

Active ingredient (in each tablet)

Pain reliever/fever reduce

Uses

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> COATING FREE AREA

90 TABLETS

"This product is not manufactured or distributed by Bayer Health Care, LLC., distributor of Alexe, Alexe is registered Trademark of Bayer Health Care, LLC. RD 23198



Lot

FREE AREA

COATING Exp.



NAPROXEN SODIUM

naproxen sodium tablet

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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
ı	NARROWEN CORNER (UNIV. OTNOTCOADO) (NARROWEN, UNIV. ETVICEDATO)	NARROWEN CORUM	220

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			

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