

SIGNATURE CARE NAPROXEN SODIUM- naproxen sodium tablet, film coated Safeway

Better Living Brands LLC Naproxen Sodium Drug Facts

Active ingredient (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

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 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.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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 | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • ask a doctor |

Other information

- **each caplet contains:** sodium 22 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 no. 2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

EASY TO OPEN CAP

Compare to Aleve® Caplets active ingredient

Signature Care®

Quality Guaranteed

Naproxen Sodium

TABLETS, 220 mg

Pain Reliever/Fever Reducer (NSAID)

Strength to last 12 hours

Actual Size

PACKAGE NOT CHILD RESISTANT

200 CAPLETS**

**Capsule-shaped tablets

DO NOT USE IF PRINTED FOL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient
(in each caplet) Naproxen Sodium 220 mg (NSAID) - fever reducer, pain reliever, and anti-inflammatory drug

Purposes
Pain relief, fever reducer, and anti-inflammatory drug

Warnings
■ stomach pain, indigestion, heartburn, or acid reflux
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■ stomach pain, indigestion, heartburn, or acid reflux

Directions
Take 1 or 2 caplets every 12 hours with food or milk. Do not take more than 2 caplets every 12 hours. Do not take more than 4 caplets every 24 hours. Do not take for more than 10 days unless directed by a doctor.

EASY TO OPEN CAP

Compare to Aleve® Caplets active ingredient**
NDC 2130-802

Quality Guaranteed

Signature Care®

Naproxen Sodium
TABLETS, 220 mg

Pain Reliever/Fever Reducer (NSAID)

Strength to last 12 hours Actual Size

PACKAGE NOT CHILD RESISTANT

200 CAPLETS** **Capsule-shaped tablets

GLUE AREA

Other Information
■ Contains 220 caplets
■ Store at 20° to 25°C (68° to 77°F), excursions permitted to 15° to 30° (59° to 86°F) [see USP Controlled Room Temperature]. Excursions are permitted to 5° to 30° (41° to 86°F) short-term excursions.

Questions or comments? 1-800-375-8200

Scan the QR code for more information.

Drug Facts (continued)

Directions
Take 1 or 2 caplets every 12 hours with food or milk. Do not take more than 2 caplets every 12 hours. Do not take more than 4 caplets every 24 hours. Do not take for more than 10 days unless directed by a doctor.

Warnings
■ stomach pain, indigestion, heartburn, or acid reflux
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ADHESIVE AREA NO COPY

| SIGNATURE CARE NAPROXEN SODIUM | | | |
|-------------------------------------|----------------|---------------------------|---------------|
| naproxen sodium tablet, film coated | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:21130-802 |
| 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) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|----------|
| Color | BLUE (light blue) | Score | no score |
| Shape | OVAL | Size | 12mm |
| Flavor | | Imprint Code | L368 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:21130-802-82 | 200 in 1 BOTTLE; Type 0: Not a Combination Product | 07/02/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA074661 | 07/02/2018 | |

Labeler - Safeway (009137209)

Revised: 11/2021

Safeway