

**NAPROXEN SODIUM- naproxen sodium tablet
CVS**

Naproxen Sodium TABLETS, 220 mg (NSAID)
Pain reliever/ fever reducer
GLUTEN FREE
270 CAPLETS†
†Capsule-shaped tablets**

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

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 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 had 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 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 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

- 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?

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

Principal display panel

CVS Health. Compare to the active ingredient in Aleve® Caplets*
NDC 51316-762-70

Naproxen Sodium

TABLETS, 220 mg (NSAID)**
Pain reliever/fever reducer
GLUTEN FREE

STRENGTH TO LAST 12 HOURS

Actual Size
270 CAPLETS*
*Capsule-shaped tablets

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. DO NOT USE IF FOIL INNER SEAL IS BROKEN OR MISSING.

Drug Facts
Active ingredient (in each caplet)
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
 ■ temporarily reduces fever

Warnings
Alergy 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 redness ■ 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

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 P-00-51316-762
 Made in India W-9638
 Lot: 20000005138
 Exp: 70000003338

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Inside (adhesive side)

Drug Facts (continued)

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, or 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 ■ durred 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 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 caplet every 8 to 12 hours with symptoms first
 ■ 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
 ■ 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?
 call 1-877-770-3183 Mon - Fri 8:00 AM EST to 5:00 PM PST

NAPROXEN SODIUM

naproxen sodium tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-762 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ) | NAPROXEN | 220 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| POVIDONE K30 (UNII: U725QWY32X) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL 400 (UNII: B6978945GQ) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |

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:51316-762-70 | 270 in 1 BOTTLE; Type 0: Not a Combination Product | 05/25/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091353 | 05/25/2024 | |

Labeler - CVS (062312574)

Revised: 5/2024

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