

DR SIMI ALL DAY PAIN RELIEF- naproxen sodium tablet, film coated
Farmacias De Similares TX LLC

All day Pain Relief NAPROXEN

Drug Facts

Active ingredient (in each caplet)

- Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)*

*Nonsteroidal anti-inflammatory drug

Purpose

- Pain reliever/fever reducer

Uses

- Temporarily relieves minor aches and pains due to:
- Minor pain of arthritis.
- Backache.
- Headache.
- Muscular aches.
- Menstrual cramps.
- 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.

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, or kidney disease.
- You are taking a diuretic
- You have problems or serious side effects from taking pain relievers or fever reducers.
- You have asthma.

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.
- The risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

Stop use and ask doctor if

- You experience any of the following signs of stomach bleeding:
 - Feel faint.
 - Have bloody or black stools.
 - Vomit blood.
 - Have stomach pain that does not get better.
- You have symptoms of heart problems or stroke:
- Chest Pain
- Trouble breathing
- Weakness in one side of the 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

Keep out of reach of children

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

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 over: | <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 8-12 hour period.• Do not exceed 3 caplets in a 24-hour period. |
| Children under 12 years: | Ask a doctor. |

Other information

- **Each tablet contains:** sodium 20 mg.
- Store at room temperature 15-30°C (59-86°F).
- Read all product information before use.

Inactive ingredients

Colloidal silicon dioxide, croscarmellose sodium, FD&C Blue No. 2 Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide.

Questions or comments?

(855)-280-1079

Distributed by: FARMACIAS DE SIMILARES TX LLC

800 Brazos St Ste 260, Austin, TX, 78701, USA.

customerservice@drsimi.com

www.drsimi.com

LOT #

EXP:

PEEL BACK for more DRUG FACTS

DR SIMI

NDC 85786-104-24

Strength to Last 12 hours

Naproxen Sodium 220 mg

Pain Reliever/Fever Reducer (NSAID)

24 Caplets

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PEEL BACK TO REVEAL CAPLETS

Reseal Area

Drug Facts (continued)

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- Take more or for a longer time than directed.

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| | |
|---|--|
| Drug Facts (continued) | |
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| Other information | |
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| Inactive ingredients | |
| Colloidal silicon dioxide, croscarmellose sodium, FD&C Blue No. 2 Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide. | |
| Questions or comments? (855)-280-1079 | |

DR SIMI ALL DAY PAIN RELIEF

naproxen sodium tablet, film coated

| Product Information | | | |
|---|-------------------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85786-104 |
| 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 |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | |
| POVIDONE K30 (UNII: U725QWY32X) | | | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | |
| FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584) | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | |
| Product Characteristics | | | |
| Color | blue ((Light Blue)) | Score | no score |
| Shape | OVAL ((Capsule-Shaped)) | Size | 12mm |
| Flavor | | Imprint Code | 220 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85786-104-24 | 24 in 1 BOTTLE; Type 0: Not a Combination Product | 08/18/2025 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA091353 | 08/17/2025 | |

Labeler - Farmacias De Similares TX LLC (119489934)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---|
| Granules India Limited | | 918609236 | analysis(85786-104) , label(85786-104) , manufacture(85786-104) , pack(85786-104) |

Revised: 8/2025

Farmacias De Similares TX LLC