### NAPROXEN SODIUM- naproxen sodium tablet Bi-Mart

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# **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
- 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 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 benifits of aspirin
- taking any other drug

# WHEN USING THIS PRODUCT

• take with food or milk if stomach upset occurs

# STOP USE AND ASK 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

# PREGNANCY/BREASTFEEDING

**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 (1-800-222-1222) 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 | <ul> <li>take 1 caplet every 8 to 12 hours while symptoms last</li> <li>for the first dose you may take 2 caplets within the first hour</li> <li>do not exceed 2 caplets in any 8 to 12 hour period</li> <li>do not exceed 3 caplets in a 24 hour period</li> </ul> |
|--|---|
| 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)
- DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

# **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?

call toll free **1-844-912-4012** 

Distributed by:

# **BI-MART**

Eugene, OR 97402

# **PRINCIPAL DISPLAY PANEL-100 Count**

# NDC 37835-594-01

Compare to the active ingredients in ALEVE ®\*\*

FAST LONG-LASTING PAIN RELIEF

NAPROXEN SODIUM

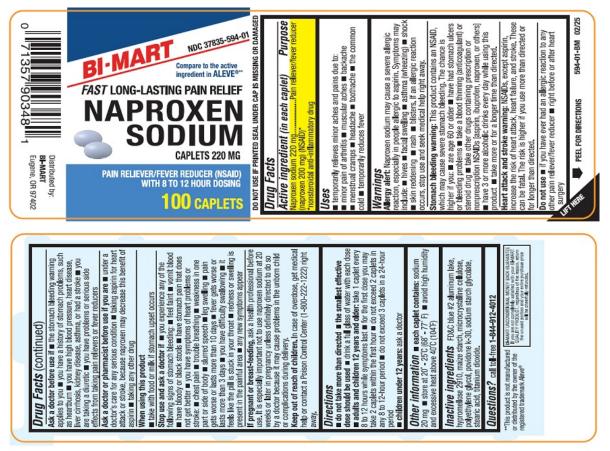
CAPLETS 220 MG

PAIN RELIEVER/FEVER REDUCER (NSAID)

WITH 8 TO 12 HOUR DOSING

100 Caplets

\*\*This product is not manufactured or distributed by the owner of the registered trademark ALEVE  $^{\ensuremath{\mathbb{R}}}$ .



# **PRINCIPAL DISPLAY PANEL-300 Count**

# NDC 37835-594-03

Compare to the active ingredients in ALEVE ®\*\*

FAST LONG-LASTING PAIN RELIEF

NAPROXEN SODIUM

# CAPLETS 220 MG

# PAIN RELIEVER/FEVER REDUCER (NSAID)

WITH 8 TO 12 HOUR DOSING

### 300 Caplets

\*\*This product is not manufactured or distributed by the owner of the registered trademark ALEVE  $^{\ensuremath{\mathbb{R}}}$  .





| NAPROXEN SODIUM   | 1                      |               |             |         |          |
|---|------------------------|---------------|-------------|---------|----------|
| naproxen sodium tablet  |                        |               |             |         |          |
| •   |                        |               |             |         |          |
| Product Information   |                        |               |             |         |          |
| Product Type  | HUMAN OTC DRUG         | ltem Code (So | urce)       | NDC:378 | 35-594   |
| Route of Administration   | ORAL                   |               |             |         |          |
|   |                        |               |             |         |          |
|   |                        |               |             |         |          |
| Active Ingredient/Active  | Moiety                 |               |             |         |          |
| Ingr  | edient Name            |               | Basis of St | rength  | Strength |
| NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ) NAPROXEN SODIUM |                        |               |             | NUM     | 220 mg   |
|   |                        |               |             |         |          |
|   |                        |               |             |         |          |
| Inactive Ingredients  |                        |               |             |         |          |
|   | Ingredient Name        | •             |             |         | Strength |
| FD&C BLUE NO. 2 ALUMINUM L  | AKE (UNII: 4AQJ3LG584) |               |             |         |          |
| HYPROMELLOSES (UNII: 3NXW29   | V3WO)                  |               |             |         |          |

| STARCH CORN    |                                    |              |          |
|----------------|------------------------------------|--------------|----------|
|                | (UNII: 08232NY3SJ)                 |              |          |
| CELLULOSE, M   | CROCRYSTALLINE (UNII: OP1R32D61U)  |              |          |
| POLYETHYLENE   | GLYCOL, UNSPECIFIED (UNII: 3WJQ05) | DW1A)        |          |
| POVIDONE K30   | (UNII: U725QWY32X)                 |              |          |
| SODIUM STARC   | H GLYCOLATE TYPE A POTATO (UNII: ! | 5856J3G2A2)  |          |
| STEARIC ACID ( | UNII: 4ELV7Z 65AP)                 |              |          |
| TITANIUM DIOX  | IDE (UNII: 15FIX9V2JP)             |              |          |
|                | aracteristics                      | <b>5</b>     |          |
| Color          | blue (Light Blue)                  | Score        | no score |
| Shape          | OVAL (Caplet -Shaped)              | Size         | 12mm     |
| Flavor         |                                    | Imprint Code | 220      |
| Contains       |                                    |              |          |
|                |                                    |              |          |
| Packaging      |                                    |              |          |

|   | i ackaging             |  |                         |                       |  |  |
|---|------------------------|--|-------------------------|-----------------------|--|--|
| - | # Item Code            | Package Description                                | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| : | NDC:37835-594-<br>01   | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/2025              |                       |  |  |
| : | 2 NDC:37835-594-<br>03 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/2025              |                       |  |  |

| Marketing Information  |            |                         |                       |  |
|--|------------|-------------------------|-----------------------|--|
| Marketing Application Number or Monograph<br>Category Citation |            | Marketing Start<br>Date | Marketing End<br>Date |  |
| ANDA A   | ANDA091353 | 09/30/2011              |                       |  |

# Labeler - Bi-Mart (027630078)

| Establishment      |         |           |                            |  |  |
|--------------------|---------|-----------|----------------------------|--|--|
| Name               | Address | ID/FEI    | <b>Business Operations</b> |  |  |
| Granules India Ltd |         | 918609236 | manufacture(37835-594)     |  |  |

Revised: 3/2025

Bi-Mart