

**BAYER ALEVE- naproxen sodium tablet**  
**Unifirst First Aid Corporation**

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**Bayer Aleve**

***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 stomach ulcers or bleeding problems  
take a blood thinner (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:** NSAID,s 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 ever have had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- 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 for more than 10 days
- fever gets worse or lasts for 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 ibuprofen at 20 weeks or later in pregnancy unless specifically 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 accidental 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 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, talc, titanium dioxide

***Questions or comments?***

**1-800-395-0689** (Mon-Fri 9AM-5PM EST)

All Day Strong

Aleve

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer

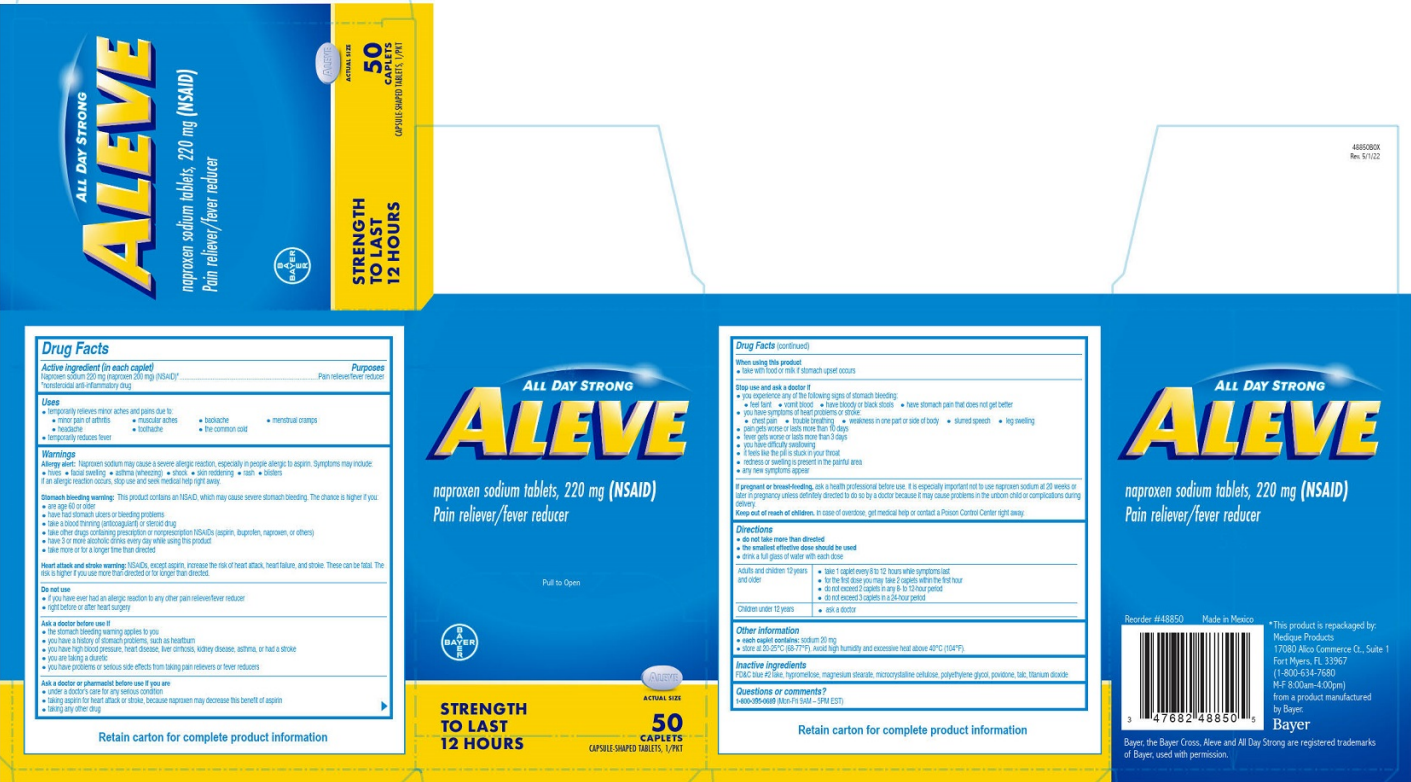
Pull To Open

Bayer

Strength To Last 12 Hours

50 Caplets

Capsule-Shaped Tablets, 1 /PKT



# BAYER ALEVE

naproxen sodium tablet

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:47682-488 |
| 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)                  |          |
| HYPROMELLOSES (UNII: 3NXW29V3WO)                    |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)               |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)      |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)            |          |
| TALC (UNII: 7SEV7J4R1U)                             |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                 |          |

## Product Characteristics

|                 |             |                     |          |
|-----------------|-------------|---------------------|----------|
| <b>Color</b>    | blue (blue) | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL (OVAL) | <b>Size</b>         | 14mm     |
| <b>Flavor</b>   |             | <b>Imprint Code</b> | ALEVE    |
| <b>Contains</b> |             |                     |          |

### Packaging

| # | Item Code        | Package Description                             | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:47682-488-50 | 50 in 1 BOX                                     | 01/24/2014           |                    |
| 1 |                  | 1 in 1 POUCH; Type 0: Not a Combination Product |                      |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| NDA                | NDA020204                                | 01/24/2014           |                    |

**Labeler** - Unifirst First Aid Corporation (832947092)

**Registrant** - Unifirst First Aid Corporation (832947092)

### Establishment

| Name                 | Address | ID/FEI    | Business Operations    |
|----------------------|---------|-----------|------------------------|
| Bayer Healthcare LLC |         | 072827066 | manufacture(47682-488) |

Revised: 1/2024

Unifirst First Aid Corporation