

**ATTACHMENT 2**

PDR for Nonprescription Drugs® and Dietary Supplements™ entry for

**ALEVE® (Bayer Consumer)**

All Day Strong  
naproxen sodium tablets, 220 mg  
Pain reliever/fever reducer

ALEVE® Caplets \* , Gelcaps \*\* , or Tablets  
Naproxen Sodium Tablets, USP

**Active Ingredient:**  
**(in each tablet/caplet/gelcap)**

**Purpose:**

Naproxen sodium 220 mg (naproxen 200 mg) ..... Pain reliever/Fever reducer

**Uses:** Temporarily relieves minor aches and pains due to:

- common cold
- headache
- toothache
- muscular aches
- backache
- menstrual cramps
- minor pain of arthritis

temporarily reduces fever

**Warnings: Allergy Alert:** Naproxen sodium may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain relievers/fever reducers. Naproxen sodium may cause stomach bleed

**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer

**Ask a doctor before use if you have** had serious side effects from any pain reliever/fever reducer

**Ask a doctor or pharmacist before use if you are**

- taking any other product that contains naproxen sodium or any other pain reliever/fever reducer
- taking other drugs on a regular basis
- under a doctor's care for any continuing condition

**Stop use and ask a doctor if:**

- an allergic reaction occurs. Seek medical help right away.
- any new or unexpected symptoms occur
- symptoms continue or worsen
- you have difficulty swallowing or it feels like the pill is stuck in your throat
- you develop heartburn
- stomach pain occurs with use of this product or if even mild symptoms persist
- pain worsens or lasts for more than 10 days
- fever lasts for more than 3 days
- painful area is red or swollen

**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.

**Directions:**

- do not take more than directed
- **drink a full glass of water with each dose**

**ALEVE® Caplets**

Over age 65	1 caplet every 12 hours. Do not exceed 1 caplet in 12 hours, unless directed by a doctor.
12-65 years	take 1 caplet every 8 to 12 hours. For the first dose you may take 2 caplets within the first hour. Do not take more than 2 caplets in any 8 to 12 hours, or 3 caplets in a 24 hour period. The smallest effective dose should be used.
under 12 years	• ask a doctor

**ALEVE® Gelcaps**

Over age 65	1 gelcap every 12 hours. Do not exceed 1 gelcap in 12 hours, unless directed by a doctor.
12-65 years	take 1 gelcap every 8 to 12 hours. For the first dose you may take 2 gelcaps within the first hour. Do not take more than 2 gelcaps in any 8 to 12 hours, or 3 gelcaps in a 24 hour period. The smallest effective dose should be used.
under 12 years	• ask a doctor

**ALEVE® Tablets**

Over age 65	1 tablet every 12 hours. Do not exceed 1 tablet in 12 hours, unless directed by a doctor.
12-65 years	take 1 tablet every 8 to 12 hours. For the first dose you may take 2 tablets within the first hour. Do not take more than 2 tablets in any 8 to 12 hours, or 3 tablets in a 24 hour period. The smallest effective dose should be used.
under 12 years	• ask a doctor

**Other Information:**

- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat 40°C (104°F)

**ALEVE® Caplets**

- **each caplet contains:** sodium 20 mg

**ALEVE® Gelcaps**

- **each gelcap contains:** sodium 20 mg

**ALEVE® Tablets**

- **each tablet contains:** sodium 20 mg

**Inactive Ingredients:**

**ALEVE® Caplets:** Magnesium stearate, microcrystalline cellulose, opadry YS-1-4215, povidone, talc.

**ALEVE® Gelcaps:** D&C yellow #10 lake, disodium EDTA, edible ink, FD&C blue #1, FD&C yellow # lake, gelatin, glycerin, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, talc, titanium dioxide, triacetin.

**ALEVE® Tablets** Magnesium stearate, microcrystalline cellulose, opadry YS-1-4215, povidone, talc.

\* capsule-shaped tablet(s)

\*\* gelatin coated capsule-shaped tablet(s)

**How Supplied:**

**ALEVE® Caplets** in boxes of 8, 24, 50, 100, 150, 200.

**ALEVE® Gelcaps** in boxes of 20, 40, 80.

**ALEVE® Tablets** in boxes of 24, 50, 100, 150.

**Questions or comments?** call 1-800-395-0689 or [www.aleve.com](http://www.aleve.com)

Do not use if carton is open or if foil seal imprinted with "Safety *SQUEASE* ®" on bottle opening is miss or broken.

Distributed by

Bayer Corporation

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Morristown, NJ 07962-1910 USA

B-R LLC

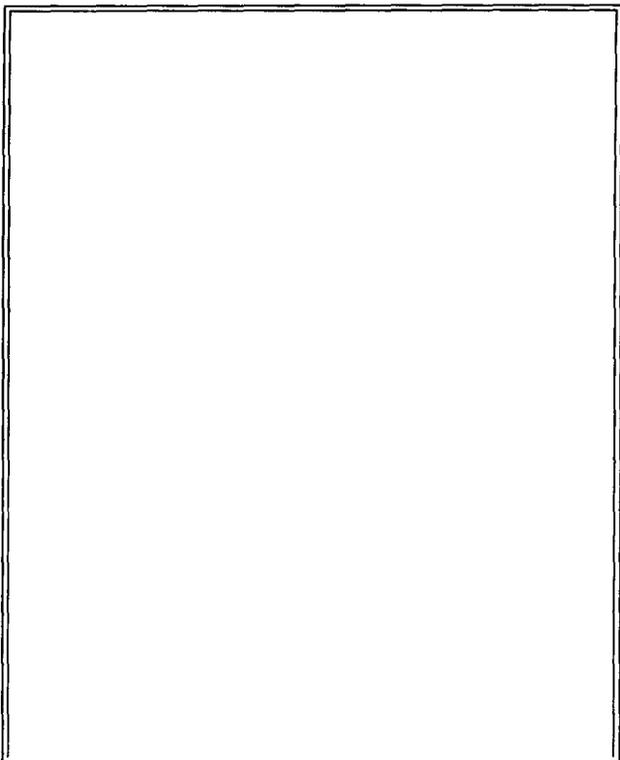
*Read Consumer*

*Leaflet Before Use*

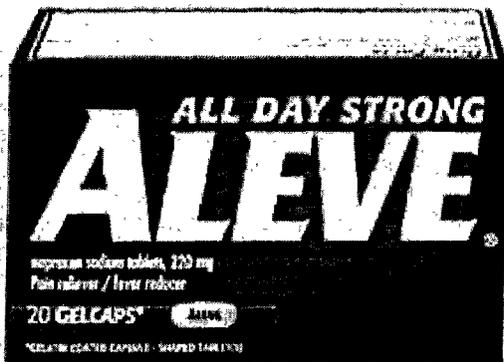
**PRODUCT PHOTO(S):**

NOTE: These photos can be used only for identification by shape, color, and imprint. They do not depict actual *or relative* size.

The product samples shown here have been supplied by the manufacturer and reproduced in full color by as a quick-reference identification aid. While every effort has been made to assure accurate reproduction, please remember that any visual identification should be considered preliminary. In cases of poisoning or suspected overdose, the drug's identity should be verified by chemical analysis.



**Bayer Corporation  
Consumer Care Division**



Tablets and Caplets available in  
24, 50, 100 and 150 count.  
Caplets also available in 200 count.  
Gelcaps available in 20, 40  
and 80 count.

**Aleve®**

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