ALEVE- naproxen sodium capsule, liquid filled
Bayer HealthCare LLC.

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ALEVE ®

LIQUID GELS

Drug Facts

Active ingredient (in each capsule)
Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) ¹

¹ nonsteroidal anti-inflammatory drug

Uses

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 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 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
• pain gets worse or lasts more than 10 days
• fever gets worse or lasts more than 3 days
• redness or swelling is present in the painful area
• any new symptoms appear
• you have difficulty swallowing
• it feels like the capsule is stuck in your throat

**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
• the smallest effective dose should be used
• drink a full glass of water with each dose
• if taken with food, this product may take longer to work

| Adults and children 12 years and older: | • take 1 capsule every 8 to 12 hours while symptoms last  
|                                          | • for the first dose you may take 2 capsules within the first hour  
|                                          | • do not exceed 2 capsules in any 8- to 12-hour period  
|                                          | • do not exceed 3 capsules in a 24-hour period |

| Children under 12 years:                 | • ask a doctor |

Other information

• each capsule contains: sodium 20 mg
• store at 20-25°C (68-77°F) avoid high humidity and excessive heat above 40°C (104°F)
• read all directions and warnings before use. Keep carton.

Inactive ingredients

FD&C blue #1, gelatin, glycerin, lactic acid, mannitol, pharmaceutical ink, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol

Questions or comments?

1-800-395-0689
(Mon – Fri 9AM – 5PM EST) or www.aleve.com

Distributed by:
Bayer HealthCare LLC
Consumer Care
P.O. Box 1910
Morristown, NJ 07962-1910 USA

PRINCIPAL DISPLAY PANEL - 220 mg Capsule Bottle Carton

See new warnings information

ALEVE®

LIQUID GELS

naproxen sodium capsules, 220 mg (NSAID)

pain reliever/fever reducer

Bayer HealthCare

• ALL DAY STRONG® •

12 HOURS STRONG

40
**Product Information**

<table>
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<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:0280-6080</th>
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<tr>
<td>Route of Administration</td>
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**Active Ingredient/Active Moiety**

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)</td>
<td>NAPROXEN SODIUM</td>
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**Inactive Ingredients**

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<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
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<tr>
<td>GELATIN (UNII: 2G86QN327L)</td>
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<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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<tr>
<td>MANNITOL (UNII: 3OWL53L36A)</td>
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<td>Povidone K30 (UNII: U725QWY32X)</td>
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<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
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<td>WATER (UNII: 059QF0KO0R)</td>
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<td>SORBITOL (UNII: 506T60A25R)</td>
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**Product Characteristics**

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**Packaging**

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### Marketing Information

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**Labeler** - Bayer HealthCare LLC. (112117283)

Revised: 11/2019