

**ALEVE CAPLETS - EASY OPEN ARTHRITIS CAP- naproxen sodium tablet**  
**Bayer HealthCare LLC.**

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**Aleve** ®

**Caplets - Easy Open Arthritis Cap**

***Drug Facts***

**Active ingredient (in each caplet)**

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) <sup>1</sup>

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<sup>1</sup> 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 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 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 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 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**

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

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|--|---|
| • Adults and children 12 years and older | • take 1 tablet every 8 to 12 hours while symptoms last           |
|  | • for the first dose you may take 2 tablets within the first hour |
|  | • do not exceed 2 tablets in any 8- to 12-hour period             |
|  | • do not exceed 3 tablets in a 24-hour period                     |
| • Children under 12 years                | • ask a doctor  |
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### **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, hypromelloses, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidones, talc, titanium dioxide

### **Questions or comments?**

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

Dist. by:  
Bayer HealthCare LLC  
Whippany, NJ 07981

**PRINCIPAL DISPLAY PANEL - 270 Caplet Bottle Carton**

# SOFT GRIP® ARTHRITIS CAP

ALL DAY STRONG®

ALEVE®

naproxen sodium tablets, 220 mg (NSAID)

Pain reliever/fever reducer

THIS PACKAGE IS CHILD RESISTANT

STRENGTH TO LAST 12 HOURS

270 CAPLETS

CAPSULE-SHAPED TABLETS

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Pain reliever/fever reducer

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**270 CAPLETS**  
CAPSULE-SHAPED TABLETS

**Drug Facts**  
**Active ingredient (in each caplet)** Naproxen sodium 220 mg (naproxen 200 mg) (NSAID)\*... Pain reliever/fever reducer (nonsteroidal anti-inflammatory drug) **Purposes**  
**Uses**  
temporarily relieves minor aches and pains due to:  
• minor pain of arthritis • muscle aches  
• menstrual cramps • headache • backache  
• the common cold • toothache  
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 (wheeze) • shock  
• skin redness • 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 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 any other drug

**When using this product**  
• take with food or milk if stomach upset occurs

**Drug Facts (continued)**  
**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 of side of body  
• slurred speech • leg swelling  
• pain gets worse or lasts more than 10 days  
• lower legs 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

**Directions**  
• do not take more than directed  
• the smallest effective dose should be used  
• drink a full glass of water with each dose

**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, croscarmellose cellulose, polyethylene glycol, povidone, talc, titanium dioxide

**Questions or comments?** 1-800-395-0689 (Mon-Fri 8AM - 5PM EST)

**Do not use this product if printed safety seal bearing "Bayer HealthCare" under cap is torn or missing.**

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## ALEVE CAPLETS - EASY OPEN ARTHRITIS CAP

naproxen sodium tablet

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-6050
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 (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	blue	Score	no score
Shape	OVAL (capsule shaped tablets)	Size	12mm
Flavor		Imprint Code	Aleve
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-6050-50	1 in 1 CARTON	11/11/2013	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0280-6050-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2013	
3	NDC:0280-6050-27	1 in 1 CARTON	11/11/2013	
3		270 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:0280-6050-02	24 in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2020	
5	NDC:0280-6050-03	1 in 1 CARTON	11/11/2013	
5		130 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0280-6050-04	1 in 1 CARTON	11/11/2013	
6		150 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020204	11/11/2013	

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

Revised: 6/2020

Bayer HealthCare LLC.