

**NAPROXEN- naproxen sodium tablet**  
**Medline Industries, Inc.**

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**Naproxen**

***Drug Facts***

**Active ingredient (in each tablet)**

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:
  - headache
  - minor pain of arthritis
  - backache
  - menstrual cramps
  - muscular aches
  - 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 have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma
- you are taking a diuretic

### **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
- 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

Adults and children 12 years and older	<ul style="list-style-type: none"> <li>• take 1 tablet every 8 to 12 hours while symptoms last</li> <li>• for the first dose you may take 2 tablets within the first hour</li> <li>• do not exceed 2 tablets in any 8- to 12-hour period</li> <li>• do not exceed 3 tablets in a 24-hour period</li> </ul>
Children under 12 years	<ul style="list-style-type: none"> <li>• ask a doctor</li> </ul>

### Other information

- **each tablet contains:** sodium 20 mg
- store at room temperature. Avoid excessive heat above 40°C (104°F).
- read all warnings and directions before use. Keep carton

### 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 or comments?

Call toll free 1-800-MEDLINE (633-5463) Monday-Friday 9am-5pm cst)

Dist. by:

Medline Industries, Inc.

Mundelein, IL 60060

### PRINCIPAL DISPLAY PANEL – 100 Tablet Bottle Carton

*Medline*

*NDC53329-675-30*

**\*\*Compare to the active ingredient in Aleve**

**Naproxen**  
**Pain Reliever/**  
**Fever Reducer (NSAID)**  
**Strength to last 12 Hours**  
**Naproxen Sodium Tablets**  
**220 mg**  
**100 Tablets – 220 mg each**

NO PRINT  
NO VARNISH  
NO COATING

NDC 53329-675-30

## NAPROXEN

**PAIN RELIEVER/  
FEVER REDUCER (NSAID)**

**STRENGTH TO LAST 12 HOURS**

Naproxen Sodium Tablets

220 mg

**100 Tablets - 220 mg each**

NO PRINT  
NO VARNISH  
NO COATING

Lot No.:  
Exp. Date:

R144UL  
PDA  
R001977 Product of India

8 84389 82337 1

**Drug Facts (continued)**

**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)
  - rash
  - blisters
- If an allergic reaction occurs, stop use and seek medical help right away.
- Some do not take this medicine.** 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
  - have 3 or more alcoholic drinks every day while using this product
  - take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
  - 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

100 Tablets - 220 mg each

220 mg

Naproxen Sodium Tablets

**NAPROXEN**  
(NSAID)  
PAIN RELIEVER/  
FEVER REDUCER

**Drug Facts (continued)**

**Warnings**

- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under 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
  - have bloody or black stools
  - vomit blood
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever develops or lasts more than 3 days
- redness or swelling is present in the painful area
- new symptoms appear
- you have difficulty swallowing
- it feels like the pills stuck to 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 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 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 tablet every 8 to 12 hours while symptoms last

**Drug Facts (continued)**

**Warnings**

- for the first day, 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

**Other information**

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

**Inactive ingredients** FDC Blue #2 aluminum lake, hydroxytoluene 2510, maize starch, microcrystalline cellulose, polyethylene glycol, povidone K-30, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**  
 Call toll free 1-800-MEDLINE (633-6463)  
 Monday-Friday 9AM-5PM CST

\*This product is not manufactured or distributed by Bayer HealthCare, LLC, owner of the registered trademark Aleve®.

Distributed by:  
 Medline Industries, Inc.  
 Mundelein, IL 60060  
 www.medline.com  
 1-800-Medline

REF: OTC523059

DO NOT USE IF INNER SEAL UNDER BOTTLE CAP IMPAIRED WITH "SPLIT" FOR TOP PROTECTION IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

**NAPROXEN**  
 naproxen sodium tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-675	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>		<b>Strength</b>	
	FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
	HYPROMELLOSES (UNII: 3NXW29V3WO)			
	STARCH, CORN (UNII: O8232NY3SJ)			
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
	POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
	POVIDONES (UNII: FZ989GH94E)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)			
	STEARIC ACID (UNII: 4ELV7Z65AP)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
<b>Product Characteristics</b>				
<b>Color</b>	BLUE (light blue)	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	8mm	
<b>Flavor</b>		<b>Imprint Code</b>	ALEVE	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53329-675-30	1 in 1 CARTON		
1		100 in 1 BOTTLE		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
NDA	NDA020204	07/26/2002		

**Labeler** - Medline Industries, Inc. (025460908)