

**NAPROXEN SODIUM- naproxen sodium tablet, coated**  
**SAM'S WEST INC**

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**NAPROXEN SODIUM**  
**TABLETS USP, 220 mg**

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

**Drug Facts**

***Active ingredient (in each tablet/caplet)***

Naproxen sodium USP, 220 mg  
(naproxen USP, 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 everyday 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 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 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 at 20 weeks or later in 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 (1-800-222-1222).

**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/caplet every 8 to 12 hours while symptoms last</li> <li>▪ for the first dose you may take 2 tablets/caplets within the first hour</li> <li>▪ do not exceed 2 tablets/caplets in any 8 to 12 hour period</li> <li>▪ do not exceed 3 tablets/caplets 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/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, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, talc, titanium dioxide

**Questions or comments?**

call toll-free weekdays 9 AM to 8 PM EST at **1-888-375-3784**

Distributed by:

**Dr. Reddy's Laboratories, Inc.**

Princeton, NJ 08540

**Made in India**

Rev: 03/2022

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL SECTION

**TAMPER EVIDENT:** Do not use if foil seal under cap printed with "sealed for your protection" is broken or missing. **IMPORTANT:** Read the directions and warnings before use.

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

150091724  
Code No: DRUGS/AP/59/97

DISTRIBUTED BY:  
SAM'S WEST, INC.  
BENTONVILLE, AR 72716

**Questions or Comments?**  
We would love to hear about your Member's Mark experience!  
Call us Toll-free at: 1-888-375-3784 from 9 a.m. - 8 p.m. EST Mon. - Fri.

 Product of India  
ISSUED 11/22

**Compare to Aleve® Caplets active ingredient\*\***

NDC 68196-255-20

**Member's Mark™**

**Naproxen Sodium**  
Tablets USP, 220 mg (NSAID)

**400 Caplets**  
(Capsule-Shaped Tablets)

**actual size**

**pain reliever  
fever reducer**

**• strength to last 12 hours**

**Compare to Aleve® Caplets active ingredient\*\***

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**Member's Mark™**

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Discard Seal, Empty & Replace Cap  
  
PLASTIC BOTTLE  
how2recycle.info  
1 93968 63033 0  
LOT: EXP:

Peel Here

<b>Drug Facts</b> <b>Active ingredient (in each caplet)</b> Naproxen sodium USP, 220 mg (naproxen USP, 200 mg) (NSAID)* *nonsteroidal anti-inflammatory drug	<b>Purposes</b> Pain reliever/ fever reducer	<b>Drug Facts (continued)</b> If an allergic reaction occurs, stop use and seek medical help right away. <b>Stomach bleeding warning:</b> 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 <b>Heart attack and stroke warning:</b> 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. <b>Do not use</b> ■ If you have ever had an allergic reaction to any other pain reliever/fever reducer	<b>Drug Facts (continued)</b> ■ right before or after heart surgery <b>Ask a doctor before use if</b> ■ 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 <b>Ask a doctor or pharmacist before use if you are</b> ■ 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 <b>When using this product</b> ■ take with food or milk if stomach upset occurs <b>Stop use and ask a doctor if</b> ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood
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<b>Drug Facts (continued)</b> ■ 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 <b>If pregnant or breast-feeding,</b> ask a health professional before use. It is especially important not to use naproxen sodium at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.	<b>Drug Facts (continued)</b> <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). <b>Directions</b> ■ do not take more than directed ■ the smallest effective dose should be used ■ drink a full glass of water with each dose <table border="1"><tr><td>Adults and children 12 years and older</td><td>■ 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</td></tr><tr><td>Children under 12 years</td><td>■ ask a doctor</td></tr></table>	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	<b>Drug Facts (continued)</b> <b>Other information</b> ■ 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). <b>Inactive ingredients</b> FD & C Blue # 2, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, talc, titanium dioxide <b>Questions or comments?</b> call toll-free weekdays 9 AM to 8 PM EST at 1-888-375-3784
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Children under 12 years	■ ask a doctor					

# NAPROXEN SODIUM

naproxen sodium tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-255(NDC:55111-273)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Naproxen Sodium</b> (UNII: 9TN87S3A3C) (Naproxen - UNII:57Y76R9ATQ)	Naproxen Sodium	220 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>hypromelloses</b> (UNII: 3NXW29V3WO)	
<b>magnesium stearate</b> (UNII: 70097M6I30)	
<b>cellulose, microcrystalline</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>povidone</b> (UNII: FZ989GH94E)	
<b>talc</b> (UNII: 7SEV7J4R1U)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	R;273
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:68196-255-20	400 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA075168	07/29/1998	

