

**NAPROXEN- naproxen tablet**  
**Safeway, Inc**

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**Pain Relief**

**Naproxen Sodium Tablets USP, 220 mg (NSAID)**  
**Pain reliever/Fever reducer**

**contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)**

**Strength to last 12 hours**

**Active Ingredient (in each caplet)**

Naproxen sodium 220mg (NSAID)

**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

**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 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.

### **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 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

### **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).





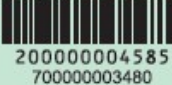


### **Inactive Ingredients**

FD&C blue#2 aluminum lake, hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone k-30, sodium starch glycolate, stearic acid, titanium dioxide

### **Questions or Comments?**

call 1 -877-770-3183 Mon – Fri 8:00 AM EST to 5:00 PM PST

Principal Display Panel

<p>COATING FREE AREA</p> <p>700000004585 200000003480</p> 	 <p>MADE IN INDIA</p>  <p>Scan here for more information</p> <p>Signature Care, Inc. 21000 Folsom, CA 95630-9000 1-877-770-3183</p>  <p>PAPER BOX PLASTIC BOTTLE</p>	<p>size : 1-3/4 X 1+3/4 X 3+3/8 ref # : PP180604B material : .016 SBS</p>	
<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>Have 3 or more alcoholic drinks every day while using this product</li> <li>Take more or for a longer time than directed</li> </ul> <p><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.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>If you have ever had an allergic reaction to any other pain reliever/fever reducer</li> <li>Right before or after heart surgery</li> </ul> <p><b>Ask a doctor before use if</b></p> <ul style="list-style-type: none"> <li>The stomach bleeding warning applies to you</li> <li>You have a history of stomach problems, such as heartburn</li> <li>You have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke</li> <li>You are taking a diuretic</li> <li>You have problems or serious side effects from taking pain relievers or fever reducers</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are</b></p> <ul style="list-style-type: none"> <li>Under a doctor's care for any serious condition</li> <li>Taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin</li> <li>Taking any other drug</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>Take with food or milk if stomach upset occurs</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>You experience any of the following signs of stomach bleeding:             <ul style="list-style-type: none"> <li>Red, black, or white stool</li> <li>Dark, bloody, or black stools</li> <li>Severe stomach pain that does not get better</li> </ul> </li> <li>You have symptoms of heart problems or stroke:             <ul style="list-style-type: none"> <li>Chest pain</li> <li>Trouble breathing</li> <li>Weakness in one part or side of body</li> <li>Sudden speech</li> <li>Leg swelling</li> </ul> </li> <li>Pain gets worse or lasts more than 10 days</li> <li>Fever gets worse or lasts more than 3 days</li> <li>You have difficulty swallowing</li> </ul>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>If tablets (like the pill) is stuck in your throat</li> <li>Restless or swelling is present in the painful area</li> <li>Any new symptoms appear</li> </ul> <p><b>If pregnant or breast-feeding, ask a health professional before use.</b> 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.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> or do not take more than directed</p> <ul style="list-style-type: none"> <li>Take the smallest effective dose should be used</li> <li>Drink a full glass of water with each dose</li> </ul> <p><b>Adults and children 12 years and older</b></p> <ul style="list-style-type: none"> <li>Take 1 caplet every 8 to 12 hours while symptoms last</li> <li>For the first dose you may take 2 caplets within the first hour</li> <li>Do not exceed 2 caplets in any 8- to 12-hour period</li> <li>Do not exceed 3 caplets in a 24-hour period</li> </ul> <p><b>Children under 12 years</b></p> <ul style="list-style-type: none"> <li>Ask a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>Each caplet contains sodium 20 mg</li> <li>Store at 20° - 25°C (68° - 77°F). Avoid high humidity and excessive heat above 40°C (104°F).</li> </ul> <p><b>Inactive ingredients</b></p> <p>FD&amp;C Blue #2 aluminum lake, hydroxyethylcellulose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, povidone I-30, sodium starch glycolate, stearic acid, titanium dioxide</p> <p><b>Questions or comments?</b></p> <p>Call 1-877-770-3183 Mon – Fri 8:00 AM EST to 5:00 PM PST</p>	<p>Signature Care</p> <p>Compare to Aleve® Caplets active ingredient*</p> <p>NDC 2130-062-05</p>	<p><b>Important: Read all warnings and directions before use. Keep carton for important information.</b></p> <p><b>DO NOT USE IF CARTON IS OPEN OR IF FOIL SEAL ON BOTTLE OPENING IS MISSING OR BROKEN</b></p>
<p>COATING FREE AREA</p> <p>200000004585 700000003480</p> 	<p><b>Pain Relief</b></p> <p><b>NAPROXEN SODIUM TABLETS, USP 220 mg (NSAID)**</b></p> <p><b>Pain Reliever/Fever Reducer</b></p> <p>Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)</p> <p><b>STRENGTH TO LAST 12 HOURS</b></p> <p>Actual Size</p>  <p><b>50 CAPLETS*</b> (*Capsule-Shaped Tablets)</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each caplet)</b> Naproxen sodium 220 mg <b>Purposes</b> Pain reliever/fever reducer (naproxen 200 mg) (NSAID)** **nonsteroidal anti-inflammatory drug</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>Temporarily relieves minor aches and pains due to:             <ul style="list-style-type: none"> <li>Minor pain of arthritis</li> <li>Backache</li> <li>Headache</li> <li>The common cold</li> <li>Temporarily reduces fever</li> </ul> </li> <li>Muscular aches</li> <li>Menstrual cramps</li> <li>Toothache</li> </ul> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:</p> <ul style="list-style-type: none"> <li>Hives</li> <li>Facial swelling</li> <li>Skin reddening</li> <li>Rash</li> <li>Blister</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p> <p><b>Stomach bleeding warning:</b> This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:</p> <ul style="list-style-type: none"> <li>Are age 60 or older</li> <li>Have had stomach ulcers or bleeding problems</li> <li>Take a blood thinning (anticoagulant) or steroid drug</li> <li>Take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)</li> </ul>	
<p>* This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve. Aleve is registered trademark of Bayer HealthCare, LLC.</p> <p>RD 23129</p>  <p>3 21130 77995 7</p> <p>Lot</p> <p>Exp.</p> <p>COATING FREE AREA</p>			

Principal Display Panel

size : 1+3/4 X 1+3/4 X 3+3/8  
cat # : PP180604B  
material : 016 SBS

COATING  
FREE AREA

700000004481  
200000003407

**Drug Facts (continued)**

- Have 2 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 risks are 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 is 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: ● red, black, or tarry stool ● vomit blood ● brown, bloody or black stool  
● you 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 ● big swelling
- pain gets worse or lasts more than 10 days ● fever gets worse 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
- pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium at 28 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.

**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 caplet every 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 12-hour period
- Do not exceed 3 caplets in a 24-hour period
- Children under 12 years ● ask a doctor

**Other information**

- Each caplet contains sodium 23 mg
- Store at 20°-25°C (68°-77°F), avoid high humidity and excessive heat above 40°C (104°F).

**Inactive ingredients** FDAC (as  $\text{H}_2$  aluminum lake), hypromellose 2910, maize starch, microcrystalline cellulose, polyethylene glycol, croscarmellose, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**  
call 1-877-709-6165 Mon - Fri 8:00 AM EST to 5:00 PM PST.



MADE IN INDIA



Compare to Aleve<sup>®</sup> Caplets active ingredient<sup>1</sup>

NDC 2700-063-09

**Pain Relief**  
NAPROXEN SODIUM TABLETS, USP 220 mg (NSAID)\*\*

**Pain Reliever/Fever Reducer**  
Contains no ingredient made from a gluten-containing grain (wheat, barley, rye)

STRENGTH TO LAST 12 HOURS

Actual Size

90 CAPLETS<sup>1</sup>  
 (Capsule-Shaped Tablets)



<sup>1</sup>This product is not manufactured or distributed by Bayer HealthCare, LLC, distributor of Aleve. Aleve is a registered Trademark of Bayer HealthCare, LLC.



Lot  
Exp.

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Important: Read all warnings and directions before use. Keep caplets for important information.

**DO NOT USE IF CAPTOPRIL OPEN OR IF SEAL ON BOTTLE OPENING IS MISCUT OR BROKEN.**

**Drug Facts**

**Active ingredient (in each caplet)**  
Naproxen sodium 220 mg  
**Pain reliever/fever reducer**  
naproxen 220 mg (NSAID)  
\*\*nonsteroidal anti-inflammatory drug

**Uses**

- Temporarily relieves minor aches and pains due to:   
● minor pain of arthritis ● muscle aches
- headache ● menstrual cramps
- 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 (wheezing)
- 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 55 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)

Principal Display Panel



<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

### Product Characteristics

<b>Color</b>	blue (light blue)	<b>Score</b>	no score
<b>Shape</b>	OVAL ((Caplet -Shaped))	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	220
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-062-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2023	
2	NDC:21130-062-09	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2023	
3	NDC:21130-062-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/30/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	08/30/2023	

**Labeler** - Safeway, Inc (009137209)

Revised: 12/2023

Safeway, Inc