

**NAPROXEN SODIUM- naproxen sodium tablet, coated**  
**AMERIFOODS TRADING COMPANY**

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**1145-FIR-2025-0714**

***Drug Facts***

**Active ingredient (in each caplet)**

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID) \*

\*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 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. (1-800-822-1222)

### 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 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>
Children under 12 years	<ul style="list-style-type: none"> <li>■ ask a doctor</li> </ul>

### 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

croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

### Questions or comments?

1-844-705-4384

### PRINCIPAL DISPLAY PANEL

FIRST STREET®

NDC 61504-145-02

†COMPARE TO THE ACTIVE INGREDIENT IN ALEVE®

Naproxen Sodium

Tablets, 220 mg

Pain Reliever/Fever Reducer (NSAID)

STRENGTH TO LAST 12 HOURS

ACTUAL SIZE

\*\*Capsule-Shaped Tablets

50 CAPLETS\*\*

INK AND COATING FREE  
FOR LOT AND  
EXPIRATION STAMPING



DO NOT USE IF IMPRINTED SEAL  
UNDER CAP IS BROKEN OR MISSING

This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Aleve®

**Drug Facts**

**Active ingredient (in each caplet)**

Naproxen sodium 220 mg  
(naproxen 200 mg) (NSAID)\*

**Purposes**

- Pain reliever/fever reducer
- temporarily reduces fever
- minor pain of arthritis
- muscular aches
- menstrual cramps
- toothache
- headache
- the common cold

**Uses**

- temporarily relieves minor aches and pains due to:
- minor pain of arthritis
- muscular aches
- menstrual cramps
- toothache
- headache
- the common cold

**Warnings**

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

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- shock
- skin redness
- rash
- blisters

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**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.

**Drug Facts (continued)**

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**

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- 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
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**When using this product**

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**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
- chest pain
- trouble breathing
- dizziness
- 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

**Drug Facts (continued)**

- 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**

- 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).

KEEP CARTON FOR REFERENCE  
DISTRIBUTED BY: AMERIFOODS TRADING CO.  
P.O. BOX 512377  
LOS ANGELES, CA 90051-0377  
100% SATISFACTION GUARANTEED  
OR YOUR MONEY BACK

Questions or comments?  
1-844-705-4384

**Drug Facts (continued)**

**Inactive ingredients** croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

NDC 61504-145-02  
\*COMPARE TO THE ACTIVE INGREDIENT IN ALEVE®  
**STRENGTH TO LAST 12 HOURS**  
ACTUAL SIZE  
**50 CAPLETS\*\***



**Naproxen Sodium**  
Tablets, 220 mg  
Pain Reliever/Fever Reducer (NSAID)  
\*\*Capsule-Shaped Tablets

NC

NC

COATING FREE AREA

**NAPROXEN SODIUM**

naproxen sodium tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61504-145
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYVINYL ALCOHOL</b> (UNII: 532B59J990)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL (Biconvex)	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	I7
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61504-145-02	1 in 1 CARTON	10/30/2023	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	10/30/2023	

**Labeler** - AMERIFOODS TRADING COMPANY (626388680)

Revised: 7/2025

AMERIFOODS TRADING COMPANY