

**PAIN RELIEF- naproxen sodium tablet, film coated**  
**Gobrandts, Inc**

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**Pain Relief**

**Naproxen Sodium**

***Drug Facts***

***Active Ingredient (in each tablet)***

Naproxen Sodium 220 mg\*\*

\*\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever/fever reducer

***Uses***

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

***Warnings***

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

Symptoms may include:

- asthma (wheezing)
- blisters
- facial swelling
- hives
- rash
- shock
- skin reddening

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains a nonsteroidal anti-inflammatory drug (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 you**

- 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 if you are**

- under a doctor's care for any serious condition
- taking any other drug
- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin

**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: n feel faint n 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 n 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 (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

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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>

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### ***Other information***

- **each tablet contains: sodium 20 mg**
- store between 20°-25°C (68°-77°F). Avoid high humidity and excessive heat above 40°C (104°F)

### ***Inactive ingredients***

Microcrystalline cellulose, Starch, Sodium starch glycolate, povidone (K-30), stearic acid, purified water, hydroxy propyl methylcellulose, polyethylene glycol, titanium dioxide, FD&C Blue #2 aluminum lake

### ***Questions or comments?***

**1-888-333-9792**

### **PRINCIPAL DISPLAY PANEL**

Compare to the active ingredient in Aleve

NDC 82501-1576-1

Good now

12 HOUR

Pain Relief

Naproxen Sodium Tablets, 220 mg

100 TABLETS

Pain Reliever + Fever Reducer (NSAID)

**Drug Facts (continued)**

**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**

- taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- 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
  - have bloody or black stools
- 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
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- you have symptoms of heart problems or stroke:
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  - trouble breathing
  - slurred speech
  - leg swelling
  - weakness in one part or side of body
  - 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. (1-800-222-1222)

**Directions**

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adults & children 12 years & 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	ask a doctor

**Other information**

- each tablet contains: sodium 20 mg
- store between 20-25°C (68-77°F). Avoid high humidity and excessive heat above 40°C (104°F).

**Inactive ingredients**

Microcrystalline cellulose, maize starch, sodium starch glycolate, povidone (K-30), stearic acid, purified water, hydroxypropyl methylcellulose, polyethylene glycol, titanium dioxide, FD&C Blue #2 Aluminum Lake

**Questions or comments? 1-888-333-9792**

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

## PAIN RELIEF

naproxen sodium tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82501-1576
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
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<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, POTATO</b> (UNII: 8I089SAH3T)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>METHYLCELLULOSE, UNSPECIFIED</b> (UNII: Z944H5SN0H)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<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:82501-1576-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/30/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	05/30/2022	

**Labeler** - Gobrands, Inc (057499049)

Revised: 12/2024

Gobrands, Inc