

**PAIN AND FEVER RELIEF- naproxen sodium tablet**  
**Pioneer Life Sciences, LLC**

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**Active Ingredient**

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

\*nonsteroidal anti-inflammatory drug

**Purpose**

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.

### **Ask Doctor:**

- 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 DOCTOR/PHARMACIST:**

- under a doctor's care for any serious condition
- taking any other drug

### **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

You may report side effects to FDA at 1-800-FDA-1088

### **PREGNANCY**

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**

Adults and children 12 years and over

- take 1 tablet every 8 to 12 hours while symptoms last
- for the first dose 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 hr period

Children under 12 years

- ask a doctor

## **OTHER INFORMATION**

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

## **INACTIVE INGREDIENTS**

Polyvinyl Pyrolidone, Microcrystalline Cellulose, Starch 1500, Sodium Starch Glycolate, Talc, Magnesium Stearate, FD&C Blue #2, Purified Water, Polysorbate 80, Titanium Dioxide, Polyethylene Glycol, Hypromellose

## **QUESTIONS OR COMMENTS?**

Call 1-732-698-5070 Monday through Friday 9AM-5PM EST or [www.pioneerlifesciences.com](http://www.pioneerlifesciences.com)

### **Do not Use:**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

### **When using this product**

- take with food or milk if stomach upset occurs

## **PRINCIPAL DISPLAY PANEL**



Size: 7.5"x3.125" • Date: Sat, May 15, 2021 • Peel Off Label

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 or right before or after surgery. Ask a doctor before use if you have a history of stomach bleeding problems, such as heartburn or you have a high blood pressure, heart disease, liver cirrhosis, or kidney disease. If you are taking a diuretic you have problems or serious side effects from taking pain relievers or fever reducers you have asthma. Ask a doctor or pharmacist before use if you are under a doctor's care for any serious conditions. Ask your doctor if you are taking this product 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 in your stool, black stools, have stomach pain that does not get better, pain gets worse or lasts more than 3 days, you have difficulty swallowing, it feels like the pit is stuck in your throat, redness or swelling is present in the painful area, or you have 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. Use the smallest effective dose. Should be used with a full glass of water with each dose. Adults and children 12 years of age or older: take 1 tablet 8 to 12 hours while symptoms last. For the first dosage you may take 2 tablets within the first hour. Do not exceed 2 tablets in any 8 to 12 hours 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 VERY LOW SODIUM. Store at 20° to 25° C (68° to 77° F) (104° F). Reseal at product information before using.

**Inactive Ingredients:** Polyvinyl Pyrolidone, Microcrystalline Cellulose, Starch 1500, Sodium Starch Glycolate, Talk, Magnesium Stearate, FD&C Blue #2, Purified Water, Polysorbate 80, Tannum Dioxide, Polyethylene Glycol, Hypromellose.

**Questions or Comments?** Call 1-732-888-5070. Mon through Fri 9am - 5pm EST or www.painreliefresponse.com

This product is not manufactured or distributed by Bayer, owner of the registered trademark ALEVE® tablets.

## PAIN AND FEVER RELIEF

naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72090-003
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

**SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2)

**FD&C BLUE NO. 2** (UNII: L06K8R7DQK)

**MAGNESIUM STEARATE** (UNII: 70097M6I30)

**WATER** (UNII: 059QF0KO0R)

### Product Characteristics

<b>Color</b>	blue ((Light Blue))	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	ET;9
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-003-01	300 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207612	05/19/2021	

**Labeler** - Pioneer Life Sciences, LLC (014092742)

Revised: 5/2021

Pioneer Life Sciences, LLC