

**NAPROXEN SODIUM- naproxen sodium tablet  
Granules USA, Inc.**

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**Naproxen Sodium Tablets, USP 220 mg (NSAID)\*\*  
Pain reliever/fever reducer  
*STRENGTH TO LAST 12 HOURS***

**Active ingredient (For Tablet)**

(in each tablet)

Naproxen sodium 220 mg

(naproxen 200 mg) (NSAID)\*\*

\*\*nonsteroidal anti-inflammatory drug

**Active ingredient (For Caplet)**

(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

**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 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 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 the reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

### **Directions (For Tablets)**

- **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 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- hour period

Children under 12 years

- ask a doctor

### **Directions (For Caplets)**

- **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 (For Tablet)**

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

### **Other information (For Caplet)**

■ **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?

1-877-770-3183 Mon - Fri 9:00 AM to 4:00 PM EST.

## Tablets

<p>COATING FREE AREA</p> <p>R-00 537000020 300000431</p>	<p><b>Drug Facts (continued)</b></p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <p>Do not take more than directed. In the smallest effective dose should be used. Drink a full glass of water with each dose.</p> <p>Adults and children 12 years and older</p> <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 8 tablets in a 24-hour period</li> </ul> <p>Children under 12 years</p> <ul style="list-style-type: none"> <li>ask a doctor</li> </ul> <p><b>Other information</b></p> <p>Each tablet contains sodium 20 mg</p>	<p>size : 13/4 X 13/4 X 3/8</p> <p>ref # : PP150604B view</p> <p>material : .016 BPS date</p>	
<p><b>Drug Facts (continued)</b></p> <p>Do not use</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>Ask a doctor before use if</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 disease, 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>Ask a doctor or pharmacist before use if you are under a doctor's care for any serious condition or taking any other drug</p> <p>When using this product</p> <ul style="list-style-type: none"> <li>take with food or milk if stomach upset occurs</li> </ul> <p>Stop use and ask a dealer if</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>feel faint</li> <li>vomit blood</li> <li>have bloody or black stools</li> <li>have stomach pain that does not get better</li> </ul> </li> <li>You have symptoms of heart problems or stroke.</li> </ul>	<p><b>Drug Facts (continued)</b></p> <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>slurred speech</li> <li>leg swelling</li> <li>pain gets worse or lasts more than 10 days</li> <li>lower back worse or lasts more than 3 days</li> <li>you have difficulty swallowing</li> <li>it feels like the pill is stuck in your throat</li> <li>redness or swelling is present in the painful area</li> <li>any new symptoms appear</li> </ul> <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important that you 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 complication during delivery.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	<p><b>Drug Facts (continued)</b></p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <p>Do not take more than directed. In the smallest effective dose should be used. Drink a full glass of water with each dose.</p> <p>Adults and children 12 years and older</p> <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 8 tablets in a 24-hour period</li> </ul> <p>Children under 12 years</p> <ul style="list-style-type: none"> <li>ask a doctor</li> </ul> <p><b>Other information</b></p> <p>Each tablet contains sodium 20 mg</p>	<p>KEEP CAUTION FOR REFERENCE</p> <p>DO NOT USE IF CAPSULE IS OPEN OR IF PILL, BEAD, OR BOTTLE CAPSULE IS MISSING OR DAMAGED</p> <p><b>Drug Facts</b></p> <p><b>Active ingredient</b> Purpose (in each tablet) Naproxen sodium 220 mg.....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 relieve minor aches and pains due to:             <ul style="list-style-type: none"> <li>minor pain of arthritis</li> <li>muscular aches</li> <li>headache</li> <li>backache</li> <li>toothache</li> <li>the common cold</li> <li>temporarily reduce fever</li> </ul> </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>asthma (wheezing)</li> <li>shock</li> <li>skin redness</li> <li>itching</li> <li>swelling</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 stomach drug</li> <li>take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, etc.)</li> </ul>
<p>COATING FREE AREA</p> <p>300000431 537000020 R-00</p>	<p><b>Compare to the active ingredient of Advair® Inhaler</b></p> <p><b>10 Tablets</b></p> <p><b>Naproxen Sodium Tablets USP</b></p> <p><b>220 mg (NSAID) **</b></p> <p><b>Pain reliever/fever reducer</b></p> <p><b>STRENGTH TO LAST 32 HOURS</b></p> <p>LOT: 13874 02702 4</p> <p>Exp.:</p> <p>COATING FREE AREA</p>	<p>COATING FREE AREA</p>	

## Caplets

size 15-3/4 X 5-3/4 X 3-3/8  
 cnc # : PPD866048  
 material : 016 988

COATING  
FREE AREA

700000003205  
 200000002397

**Drug Facts (continued)**

**naproxen, or aspirin**

- 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 had 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 stools
  - vomiting blood
  - have bloody or black stools

COATING  
FREE AREA

200000003205  
 700000002397

**Drug Facts (continued)**

**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
- trouble swallowing

**Stomach 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 otherwise 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 tablet every 8 to 12 hours with symptoms but
- for the first dose you may take 2 tablets with the first hour
- do not exceed 2 tablets in any 12-hour period
- do not exceed 3 tablets in a 24-hour period

**Children under 12 years**

- ask a doctor

100 Tablets

STRENGTH TO LAST 12 HOURS

Compare to the Active Ingredient of **Allevé® Tablets**

**Naproxen Sodium Tablets USP**  
**220 mg (NSAID) \*\***  
 Pain reliever/fever reducer



Compare to the Active Ingredient of **Allevé® Tablets**

Distributed by:  
 Granule Company, Inc.  
 21 Riverside Blvd., 2nd Fl.  
 Parsippany, NJ 07054  
 www.granule.com

8 13874 02054 4

Lot  
Exp.

COATING  
FREE AREA

**KEEP CAPTION FOR REFERENCE**  
**DO NOT USE IF CAPTION IS OPEN OR IF THE SEAL ON BOTTLE OPENING IS MISSING OR BROKEN**

**Drug Facts**

**Active Ingredient (in each tablet):** Naproxen sodium 220 mg Pain reliever/fever reducer (naproxen 200 mg NSAID) \*\*

**Purpose:** Intended for inflammatory drug

**Uses:**

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

**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/itching
- rash
- diarrhea

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 65 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, etc.)

CODE # 1  
 size 10-3/4 X 1-3/8 X 3-3/8  
 sku # 090816046  
 material 0.016 SBS

COATING  
FREE AREA

700000003203  
 2000000002396

**Drug Facts (continued)**

naproxen, or others.  
 ■ Take 3 or more alcoholic drinks every day while using this product.  
 ■ Take more or for a longer time than directed.  
**Heart attack and stroke warnings:** 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 had 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 the 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:

- stool that is black or dark stools
- vomit blood
- have bloody or black stools

**Drug Facts (continued)**

■ 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 ■ loss of consciousness  
 ■ 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.**

**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 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 12-hour period.  
 ■ do not exceed 3 tablets in a 24-hour period.

**Children under 12 years**  
 ■ ask a doctor

50 Tablets

STRENGTH TO LAST 12 HOURS

Pain reliever/fever reducer

220 mg (NSAID)\*\*

Naproxen Sodium Tablets USP



Compare to the Active Ingredient of Advil® Tablets

Indicated:  
 Granules  
 220 mg (NSAID)  
 11 Tablets, 100 mg  
 11 Tablets, 220 mg  
 11 Tablets, 275 mg  
 11 Tablets, 330 mg

8 13874 02053 7

Lot  
Exp.

COATING  
FREE AREA

200000003203  
 700000002396

COATING  
FREE AREA

**KEEP OUT OF REACH OF CHILDREN**

DO NOT USE IF CAPSULE IS OPEN OR IF THE SEAL ON BOTTLE OR CONTAINER SHOWS OR FEELS OPEN

**Drug Facts**

**Active ingredient** Naproxen sodium 220 mg  
**Purposes** Pain reliever/fever reducer  
**(in each tablet)** <sup>\*\*</sup>Nonsteroidal anti-inflammatory drug

**Uses**

- temporarily relieves minor aches and pains due to:  
 ■ minor pain of arthritis ■ menstrual aches  
 ■ headache ■ muscle aches  
 ■ toothache ■ backache  
 ■ 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 ■ pain redness ■ rash ■ dizziness  
 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, ...)



item	: CVS APAP SR 50CT	view
code #	:	date
size	: 1+3/4 X 1+3/4 X 3+3/8	
ref #	: PPI000049	
material	: 016 SRS	



# NAPROXEN SODIUM

naproxen sodium tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69848-010
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	



<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	220
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-010-01	10 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
2	NDC:69848-010-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	
3	NDC:69848-010-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	07/01/2019	

## NAPROXEN SODIUM

naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69848-009
<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 SODIUM	220 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>POVIDONE</b> (UNII: FZ989GH94E)
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)

### 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:69848-009-01	10 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	07/01/2019	12/31/2023

**Labeler** - Granules USA, Inc. (137098864)