

**NAPROXEN- naproxen sodium tablet**  
**NuCare Pharmaceuticals, Inc.**

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**gc 951-954L**

**Active ingredient (in each tablet)**

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

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever/ fever reducer

**Uses**

temporarily relieves minor aches and pain due to:

- backache
- muscular aches
- minor pain of arthritis
- 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**

- 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 doctor if**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have a stomach pain that dose not get better
- you have symptoms of heart problems or stroke

leg swelling  chest pain

slurred speech  trouble breathing

weakness in one part or side of body

- 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**

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 8 to 12 hour period
- do not exceed 3 tablets in a 24 hour period
- children under 12 years: ask a doctor

### **Storage**

- Store at 20-25 °C (68-77 °F). Avoid high humidity and excessive heat above 40 °C (104 °F)

### **Other information**

- **each tablet contains:** sodium 20 mg

### **Inactive ingredients**

croscarmellose sodium, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

### **Questions or comments?**

**Call 1-800-540-3765**

# Principal Display Panel


NuCare Pharmaceuticals, Inc.

**Distributed by:** 3  
Gerl-Care Pharmaceuticals Corp.  
Lakewood, NJ 08701

**Patron Instructions:**  
Packaged by:  
NuCare Pharmaceuticals, Inc.  
Orange, CA 92867

**Take** \_\_\_\_\_ **every** \_\_\_\_\_ **hours**  
\_\_\_\_\_ **times a day.**

Rev 11/01/19

**NDC: 68071-5039-3**

## Naproxen Sodium 220mg

### #30 Tablets

Each tablet contains: Naproxen Sodium 220mg (Naproxen 200mg) (NSAID)  
\* Pain Reliever/Nonsteroidal anti-inflammatory drug Fever Reducer

**Warnings/Allergy alert:** Naproxen Sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include asthma (wheezing), skin reddening, shock, hives, rash, facial swelling, hives. 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. Round shape, blue tablet imprinted "44 417" on one side.

Product #: P0343030

**Naproxen Sodium 220mg**  
Lot: 00000    NDC: 68071-5039-03  
MFR NDC: 57896-954-01    Exp.: 00-00  
Serial# 0000000002

**Naproxen Sodium 220mg**  
Lot: 00000    NDC: 68071-5039-03  
MFR NDC: 57896-954-01    Exp.: 00-00  
Serial# 0000000002



GTIN 00368071503937  
Serial# 0000000002  
Exp. Date 00-00  
LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**WARNING: KEEP OUT OF REACH OF CHILDREN**      **STORE AT CONTROLLED TEMPERATURE 68-77°F.**

## NAPROXEN

naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68071-5039(NDC:57896-954)
<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
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
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<b>Shape</b>	ROUND	<b>Size</b>	10mm	
<b>Flavor</b>		<b>Imprint Code</b>	44;417	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-5039-1	21 in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2023	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA204872	01/01/2019		

**Labeler** - NuCare Pharmaceuticals,Inc. (010632300)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	repack(68071-5039)

Revised: 7/2023

NuCare Pharmaceuticals,Inc.