

**NAPROXEN SODIUM 220MG- naproxen sodium tablet**  
**Medline Industries**

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**Naproxen Sodium 220mg Tablet**

***Active ingredient***

Naproxen Sodium 220 mg (naproxen 200 mg) (NSAID) \*non steroidal anti-inflammatory drug

***Purpose***

Pain reliever/ fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
- headache ■ muscular aches
- minor pain of arthritis ■ toothache
- backache ■ the common cold
- menstrual cramps
- 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 ■ have 3 or more alcoholic drinks every day while using this product ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ 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 have problems or serious side effects from taking pain relievers or fever reducers
- you are taking a diuretic

**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 ■ slurred speech
  - trouble breathing ■ leg swelling
  - 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
  - redness or swelling is present in the painful area
  - any new symptoms appear
  - you have difficulty swallowing
  - it feels like the pill is stuck in your throat

**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 ■ 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

### ***Other information***

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

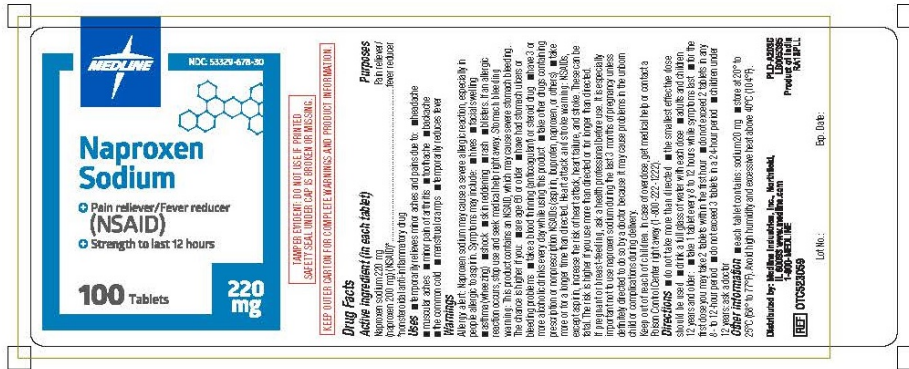
### ***Inactive ingredients***

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?***



Label Die 26.0  
1.75 x 4.75  
.125 CR



NDC 53329-678-30

MEDLINE

**Naproxen Sodium  
(NSAID)**

Pain reliever/ Fever reducer

Strength to last 12 hours

Compare to the active ingredient in Aleve (R)

**100 tablets**

**220mg**

## NAPROXEN SODIUM 220MG

naproxen sodium tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-678
<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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POVIDONE K30 (UNII: U725QWY32X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

Color	blue	Score	score with uneven pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	220
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-678-30	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2018	



### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	03/07/2018	

**Labeler** - Medline Industries (025460908)

### Establishment

Name	Address	ID/FEI	Business Operations
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Granules India Limited		918609236	manufacture(53329-678)
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Revised: 12/2019

Medline Industries