

**NAPROXEN SODIUM- naproxen sodium tablet**  
**Pharmacy Value Alliance, LLC**

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**Naproxen Sodium Tablets USP 220mg (Round)**

**Active ingredient**

(in each tablet)

Naproxen sodium 220 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

**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 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**

- **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**

- **each tablet contains:** sodium 20 mg
- store at 20 - 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?**

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



**DIE GIFCOOL**  
1.750 x 1.750 x 3.375 Flat


Note: Ensure that the unvarnished area is not less than the minimum area specified on this document.

JOB INFORMATION		HISTORY		COLORS	
 ITEM#: 30000025_CDC_Nap_Cap_100cLFC_Inda_R2 CAD#: J50009A	Version# 2				
	AS	2-19-15			
	Rev-1:	10-15-15	Rev-2:		
	Rev-2:		Rev-3:		
	Rev-3:		Rev-4:		
	Rev-4:		Rev-5:		
	Rev-5:		Rev-6:		
	Rev-6:		Rev-7:		
	Rev-7:		Rev-8:		
	Rev-8:		Rev-9:		
	Rev-9:		Rev-10:		
				Q.C.:	
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JOB INFORMATION		HISTORY		COLORS	
 ITEM#: 30000023_CDC_Np_Tib_50cLFC_Indis_R2 CAD#: J50009A	Version# 2	Printed 9-16-15		4COLOR PRO	Color
	AS	Rev-1: 10-15-15	Rev-2:	PM6 277	WFOColor
	Rev-3:	Rev-3:	PM6 285	MasterPrint	
	Rev-4:	Rev-4:	PM6 285	Coating Free	
	Rev-5:	Rev-5:	PM6 272		
	Rev-6:	Rev-6:	PM6 272		
	Rev-7:	Rev-7:	PM6 272		
	Rev-8:	Rev-8:	PM6 272		
	Rev-9:	Rev-9:	PM6 272		
	Rev-10:	Rev-10:	PM6 272		
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# NAPROXEN SODIUM

naproxen sodium tablet

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-661
Route of Administration	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)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

**Product Characteristics**

Color	blue	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	220
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-661-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016	
2	NDC:68016-661-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	02/25/2016	

**Labeler** - Pharmacy Value Alliance, LLC (101668460)

Revised: 1/2021

Pharmacy Value Alliance, LLC