

**NAPROXEN SODIUM- naproxen sodium tablet**  
**Wal-Mart Stores, Inc.,**

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**Naproxen Tablets**

**Active ingredient**

(in each caplet)

Naproxen sodium 220 mg (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

**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, or kidney disease
- 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 condition
- taking any other drug

**When using this product**

- take 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

■ have bloody or black stools

■ have stomach pain that does not get better

- 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 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**

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

### **Questions and comments?**

**1-888-287-1915**

### **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.





# NAPROXEN SODIUM

naproxen sodium tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49035-762
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:5Y76R9ATQ)	NAPROXEN SODIUM	220 mg

## Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE K30 (UNII: U725QWY32X)	

### Product Characteristics

Color	blue	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	220
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-762-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2016	
2	NDC:49035-762-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2016	
3	NDC:49035-762-21	225 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2016	
4	NDC:49035-762-30	300 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	05/25/2016	

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<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	I1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-761-21	225 in 1 BOTTLE; Type 0: Not a Combination Product	05/25/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091353	05/25/2016	

**Labeler** - Wal-Mart Stores, Inc., (051957769)