

**NAPROXEN SODIUM- naproxen sodium tablet, coated**  
**WinCo Foods, LLC**

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**WNC - 1145 - 2019-1007**

***Drug Facts***

**Active ingredient (in each caplet)**

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID <sup>1</sup>)

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<sup>1</sup> 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**

- 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 asthma
- 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
- long term continuous use may increase the risk of heart attack or stroke

#### **Stop use and ask a doctor if**

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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
- you develop heartburn
- 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**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- drink a full glass of water with each dose

adults and children 12 years and older	<ul style="list-style-type: none"> <li>• take 1 caplet every 8 to 12 hours while symptoms last</li> <li>• for the first dose you may take 2 caplets within the first hour</li> <li>• do not exceed 2 caplets in any 8- to 12-hour period</li> <li>• do not exceed 3 caplets in a 24-hour period</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>• ask a doctor</li> </ul>

### Other information

- **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).
- retain carton for complete product information

### Inactive ingredients

croscarmellose sodium, FD&C blue #2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, pregelatinized starch, talc, titanium dioxide

### Questions?

Or to report an adverse event call 800-824-1706 Monday - Friday 9am - 4pm MST

### PRINCIPAL DISPLAY PANEL

WinCo™ Foods

†Compare to the active ingredient in ALEVE®

Naproxen Sodium

Strength to Last 12 Hours

NAPROXEN SODIUM TABLETS 220 MG (NSAID)/

PAIN RELIEVER - FEVER REDUCER

50 Caplets\*\*

\*\*Capsule-shaped Tablets



## NAPROXEN SODIUM

naproxen sodium tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67091-138
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		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, CORN (UNII: O8232NY3SJ)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL (Biconvex)	Size	12mm	
Flavor		Imprint Code	I7	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-138-50	1 in 1 CARTON	12/15/2014	
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA079096		12/15/2014	

**Labeler** - WinCo Foods, LLC (056098817)