

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

WNC - 1145 - 2019-1007

Drug Facts

Active ingredient (in each caplet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID ¹)

¹ 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">• 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	<ul style="list-style-type: none">• ask a doctor

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

COATING FREE AREA

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING

0 70552123036 1



PH45020WNC_80 WFL40



DO NOT USE IF IMPRINTED SEAL
UNDER CAP IS BROKEN OR MISSING



Naproxen Sodium

NAPROXEN SODIUM TABLETS
220 mg (NSAID)/
PAIN RELIEVER - FEVER REDUCER



Strength to Last 12 Hours

**Capsule-shaped Tablets

Drug Facts (continued)

Inactive ingredients: croscarmellose sodium, FD&C blue #2, niacinogel, 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

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704
*This product is not manufactured or distributed by BAYER CONSUMER HEALTHCARE, LLC, distributor of ALEVE®.

100% SATISFACTION GUARANTEE

Comments & Questions? 800-824-1706

Drug Facts (continued)

Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer
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■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
■ you are taking a diuretic
■ you have asthma

Ask a doctor or pharmacist before use if you are
■ you have problems or serious side effects from taking pain relievers or fever reducers
■ under a doctor's care for any serious condition
■ taking any other drug

When using this product
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■ 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
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Nonsteroidal anti-inflammatory drug

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Drug Facts (continued)

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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
CROSCARMELOSE 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	

