

NAPROXEN SODIUM- naproxen sodium tablet, coated
AAA Pharmaceutical, Inc.

Naproxen Sodium Tablets

Drug Facts

Active ingredient (in each tablet)

Naproxen sodium 220 mg (naproxen 200 mg) (NSAID¹)

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

Other information

- **each tablet 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

Distributed by:

AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 24 Tablet Bottle Carton

RESTORE u

NDC 57344-144-01

†COMPARE TO THE ACTIVE
INGREDIENT IN ALEVE®

Naproxen

Naproxen Sodium Tablets, 220 mg

Pain Reliever / Fever Reducer
(NSAID)

24 COATED TABLETS

COATING FREE AREA

Drug Facts (continued)

Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer
 ■ right before or after heart surgery

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 ■ you have a history of stomach problems, such as heartburn
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 (naproxen 200 mg) (NSAID)¹.....fever reducer
 nonsteroidal anti-inflammatory drug

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 ■ take more or for a longer time than directed

INK AND COATING FREE FOR LOT AND EXPIRATION STAMPING

6 96016 18566 0



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

† This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of Aleve®

RESTORE U NDC 57344-144-01

COMPARE TO THE ACTIVE INGREDIENT IN ALEVE®

Naproxen
 Naproxen Sodium Tablets, 220 mg
 Pain Reliever / Fever Reducer (NSAID)

24 COATED TABLETS



Drug Facts (continued)

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

Distributed by:
 AAAA Pharmaceuticals, Inc.
 681 Main Street
 Lumberton, NJ 08048

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Drug Facts (continued)

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adults and children 12 years and older

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NAPROXEN SODIUM
 naproxen sodium tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-144
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 GLYCOLS (UNII: 3WJQ0SDW1A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	I3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-144-01	1 in 1 CARTON		
1		24 in 1 BOTTLE, PLASTIC		
2	NDC:57344-144-02	1 in 1 CARTON		
2		50 in 1 BOTTLE, PLASTIC		
3	NDC:57344-144-03	1 in 1 CARTON		
3		100 in 1 BOTTLE, PLASTIC		
4	NDC:57344-144-04	1 in 1 CARTON		
4		150 in 1 BOTTLE, PLASTIC		
5	NDC:57344-144-05	1 in 1 CARTON		
5		200 in 1 BOTTLE, PLASTIC		
6	NDC:57344-144-06	1 in 1 CARTON		
6		300 in 1 BOTTLE, PLASTIC		
7	NDC:57344-144-07	500 in 1 BOTTLE, PLASTIC		
8	NDC:57344-144-08	200 in 1 BOTTLE, PLASTIC		
9	NDC:57344-144-10	400 in 1 BOTTLE, PLASTIC		
10	NDC:57344-144-11	600 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079096	12/15/2012	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 12/2012

AAA Pharmaceutical, Inc.