

NAPROXEN SODIUM 220MG- naproxen sodium 220mg tablet, coated
Athlete's Needs, Inc.

Naproxen Sodium 220mg

Active ingredient

Naproxen sodium 220mg
(naproxen 200mg) (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.

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, 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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin
- 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
- 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 reach of children

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 (68-77° F)
- avoid high humidity and excessive heat above 40° C (104° F)
- do not use if tamper evident seal under bottle is broken or missing

Inactive ingredients

FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide

May contain: corn starch, croscarmellose sodium, magnesium stearate, purified water, silicon dioxide, sodium starch glycolate, stearic acid

Questions or Comments?

Call 1-800-326-8147

Principal Display Panel

Cear Choice (logo)

NAPROXEN

SODIUM

(NSAID*)

MODERN PAIN MEDICINE

PAIN & FEVER RELIEF

CONTAINS NO ASPIRIN

CAFFEINE FREE

Compare to Aleve®**

SEE NEW WARNINGS INFORMATION

50 Caplets

220 mg Each

Clear Choice

NAPROXEN SODIUM (NSAID)*
MODERN PAIN MEDICINE

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SEE NEW WARNINGS INFORMATION
50 Caplets 220 mg Each

Drug Facts

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(naproxen 200mg) (NSAID)*, fever reducer
*nonsteroidal anti-inflammatory drug

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Pain reliever/
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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.

Drug Facts (continued on inside)

Questions?
Contact A.N.I. 6029 Renaissance Place, Toledo OH 43623
Manufactured for A.N.I.
CODE 37950



LB1611
R0820

Lot No.:
Exp. Date:
PEEL HERE

Drug Facts (continued)

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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 aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin ■ 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

Drug Facts (continued)

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 ■ ask a doctor

Children under 12 years:

Other information
 ■ each caplet contains: sodium 20 mg ■ store at 20° to 25°C (68° to 77° F) ■ avoid high humidity and excessive heat above 40°C (104°F) ■ do not use if tamper evident seal under bottle is broken or missing

Inactive ingredients FD&C blue #2 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide
May contain: corn starch, croscarmellose sodium, magnesium stearate, purified water, silicon dioxide, sodium starch glycolate, stearic acid

Questions or Comments?
 Call 1-888-952-0050
 Monday through Friday 9AM- 5PM EST.

**This product is not manufactured or distributed by Bayer Healthcare, LLC, owner of the registered trademark Aleve®.

Clear Choice Naproxen

NAPROXEN SODIUM 220MG

naproxen sodium 220mg tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53185-394 |
| 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) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POVIDONE (UNII: FZ989GH94E) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL | Size | 10mm |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53185-394-50 | 50 in 1 BOTTLE; Type 0: Not a Combination Product | 12/23/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA090545 | 12/23/2014 | |

Labeler - Athlete's Needs, Inc. (619703945)