

**CLEAR CHOICE NAPROXEN SODIUM- naproxen sodium tablet**  
**Athlete's Needs Inc**

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**Clear Choice Naproxen Sodium**

**Active ingredient (in each tablet)**

Naproxen sodium 220 mg

(naproxen 200 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 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
  - 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 immediately.

**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	<ul style="list-style-type: none"><li>• take 1 tablet every 8 to 12 hours while symptoms last</li></ul>
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12 years and older	<ul style="list-style-type: none"> <li>• for the first dose you may take 2 tablets within the first hour</li> <li>• do not exceed 2 tablets in any 8- to 12-hour period</li> <li>• do not exceed 3 tablets 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 tablet 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 cap is broken or missing.

### Inactive ingredients

croscarmellose, FD&C blue no. 2, macrogol, magnesium stearate, polyvinyl alcohol, povidone, talc, titanium dioxide.

### Questions or comments?

1-800-326-8147

### Principal Display Panel

Clear Choice

Naproxen

Sodium

(NSAID)

Modern Pain Medicine

PAIN AND FEVER RELIEF

CONTAINS NO ASPIRIN

CAFFEINE FREE

Compare to Aleve®

See New Warnings Information

50 tablet

220 mg Each

Manufactured for A.N.I. Toledo OH 436253

**Clear Choice**

**NAPROXEN SODIUM (NSAID\*)**  
MODERN PAIN MEDICINE

**PAIN & FEVER RELIEF**  
**CONTAINS NO ASPIRIN**  
**CAFFEINE FREE**

**Compare To Aleve®\*\***

**SEE NEW WARNINGS INFORMATION**  
**50 Tablets      220 mg Each**

**Drug Facts**

**Active ingredient (in each tablet)**  
Naproxen sodium 220mg (naproxen 200mg) (NSAID)\* .....Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**Purposes**

**Uses** temporarily relieves minor aches and pains due to: ■ minor pain of arthritis ■ backache ■ headache ■ muscular aches ■ menstrual cramps ■ toothache ■ 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.

**Drug Facts** (continued on inside)

Manufactured for: A.M.I. Topkoo, OH 43623  
CODE 37350



LB6442  
R0812

Lot No.:  
Exp. Date:



**Drug Facts (continued)**

**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 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

**Drug Facts (continued)**

**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 immediately.

**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 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 8-12 hour period ■ do not exceed 3 tablets in a 24-hour period ■ **Children under 12 years:** ask a doctor

**Other information** ■ each tablet contains: sodium 20mg ■ 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 cap is broken or missing.**

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

**Questions or Comments?**

Call 1-800-326-8147

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

**CLEAR CHOICE NAPROXEN SODIUM**  
naproxen sodium tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53185-004	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN SODIUM	220 mg	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>		<b>Strength</b>	
	FD&C BLUE NO. 2 (UNII: L06K8R7DQK)			
	CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)			
	POLYVINYL ALCOHOL (UNII: 532B59J990)			
	POVIDONE (UNII: FZ989GH94E)			
	STARCH, CORN (UNII: O8232NY3SJ)			
	TALC (UNII: 7SEV7J4R1U)			
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
<b>Product Characteristics</b>				
<b>Color</b>	blue (Light Blue)	<b>Score</b>	no score	
<b>Shape</b>	ROUND	<b>Size</b>	9mm	
<b>Flavor</b>		<b>Imprint Code</b>	141	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:53185-004-00	1 in 1 CARTON	05/06/2013	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA079096	05/06/2013		

**Labeler** - Athlete's Needs Inc (619703945)

### Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	manufacture(53185-004)

