

**NAPROXEN SODIUM- naproxen sodium tablet, film coated**  
**Athlete's Needs Inc**

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**Clear Choice 44-604**

***Active ingredient (in each caplet)***

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:
  - headache
  - muscular aches
  - the common cold
  - toothache
  - menstrual cramps
  - backache
  - minor pain of arthritis
- temporarily reduces fever

***Warnings***

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- asthma (wheezing)
- skin reddening
- shock
- blisters
- rash
- facial swelling
- hives

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]

- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

**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, kidney disease, asthma, or had a stroke
- you have problems or serious side effects from taking pain relievers or fever reducers
- you are taking a diuretic

### **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:
  - leg swelling
  - chest pain
  - slurred speech
  - trouble breathing
  - weakness in one part or side of body
- 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 at 20 weeks or later in 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**
- 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)
- use by expiration date on package

***Inactive ingredients***

croscarmellose sodium, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

***Questions or comments?***

**Call 1-800-426-9391** 8:30 AM-4:00 PM ET, Monday-Friday

***Principal display panel***

**Clear Choice**

**NAPROXEN  
SODIUM**

**Pain Reliever  
Fever Reducer  
(NSAID)\***

**PAIN & FEVER RELIEF  
STRENGTH TO LAST 12 HOURS**

**Compare to Active  
Ingredient in Aleve®\*\***

**50 Caplets 220 mg Each**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED  
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

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

**Distributed by:** A.N.I. Toledo, OH 43623

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REV1221B60415

Clear Choice

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### Drug Facts

#### Active ingredient (in each caplet) Purpose

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

#### Uses

temporarily relieves minor aches and pains due to:  
■ headache ■ muscular aches ■ the common cold  
■ toothache ■ menstrual cramps  
■ backache ■ minor pain of arthritis  
■ temporarily reduces fever

#### Warnings

**Allergy alert:** Naproxen sodium may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

■ asthma (wheezing) ■ skin reddening ■ shock  
■ blisters ■ rash ■ facial swelling ■ hives  
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PEEL HERE FOR MORE DRUG FACTS  
REV12/18/0415

### Drug Facts (continued)

■ take more or for a longer time than directed  
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**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

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#### Stop use and ask a doctor if

■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ vomit blood  
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■ have stomach pain that does not get better  
■ you have symptoms of heart problems or stroke:  
■ leg swelling ■ chest pain  
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STOP PEELING

### Drug Facts (continued)

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■ 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  
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**Inactive ingredients** croscarmellose sodium, FD&C blue #2 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, talc, titanium dioxide

#### Questions or comments?

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Monday-Friday

Clear Choice 44-604

**NAPROXEN SODIUM**

naproxen sodium tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53185-604	
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--ALUMINUM LAKE (UNII: 4AQJ3LG584)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	44;604	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53185-604-15	50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2022	
2	NDC:53185-604-12	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/11/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA204872		03/11/2022	

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

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(53185-604)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(53185-604) , pack(53185-604)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(53185-604)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(53185-604)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(53185-604)

Revised: 11/2023

Athlete's Needs Inc