

**NAPROXEN SODIUM- naproxen sodium tablet, film coated**  
**TIME CAP LABORATORIES, INC**

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Naproxen Sodium Tablets, USP  
220 mg (NSAID)\*  
\*nonsteroidal anti-inflammatory drug

Colloidal Silicon Dioxide  
Croscarmellose Sodium  
FD&C Blue #2 Lake  
Hypromellose  
Magnesium Cellulose  
Polyethylene Glycol  
Povidone  
Titanium Dioxide

do not take more than directed  
the smallest effective dose should be used  
drink a full glass of water with each dose

temporarily relieves minor aches and pain due to:

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

Pain reliever/ Fever reducer

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

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

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 bad stomach ulcers or bleeding problems  
take a blood thinning (anticoagulant) or steroid drug  
take other drug 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.

In case of overdose, get medical help or contact a poison control center right away.

NDC 49483-609-01

**Time-Cap Labs, Inc.**  
 \*Compare to the active ingredient in Aleve® Tablets

# NAPROXEN SODIUM

Tablets USP, 220 mg (NSAID)  
 Strength to Last 12 Hours

**100** FILM-COATED BLUE TABLETS

Pain reliever/Fever reducer

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\*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark, Aleve® Tablets.  
 Made in India BGR 0316

Distributed by:  
 Time-Cap Labs, Inc.  
 7 Michael Avenue  
 Farmingdale, NY 11735

3 49483-609-01

**DAMAGED PRODUCTS DO NOT USE THIS PRODUCT IF THE IMPRINTED FOL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

**Drug Facts**

**Active Ingredient (in each tablet)**  
 Naproxen sodium 220 mg.....Pain reliever/fever reducer (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  
 ■ headache ■ menstrual cramps  
 ■ 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 redness ■ rash ■ blisters  
 If an allergic reaction occurs, stop use and seek medical help right away.

**Speech/breeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:  
 ■ are taking aspirin, other NSAIDs, or blood-thinning drugs (anticoagulants) or steroid drugs ■ 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

**SEEK MEDICAL HELP IF YOU EXPERIENCE ANY OF THE FOLLOWING FACTS**

**LOT #:** \_\_\_\_\_

**EXP. DATE:** \_\_\_\_\_

**NAPROXEN SODIUM**  
 naproxen sodium tablet, film coated

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-609
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NAPROXEN SODIUM (UNII: 9TN87S3A3C) (NAPROXEN - UNII:57Y76R9ATQ)	NAPROXEN	220 mg

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	blue	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	141
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-609-00	6500 in 1 BAG; Type 0: Not a Combination Product	03/28/2016	
2	NDC:49483-609-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2016	
3	NDC:49483-609-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/28/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090545	03/28/2016	

**Labeler** - TIME CAP LABORATORIES, INC (037052099)

**Registrant** - TIME CAP LABORATORIES, INC (037052099)

## Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-609)

Revised: 3/2016

TIME CAP LABORATORIES, INC