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

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

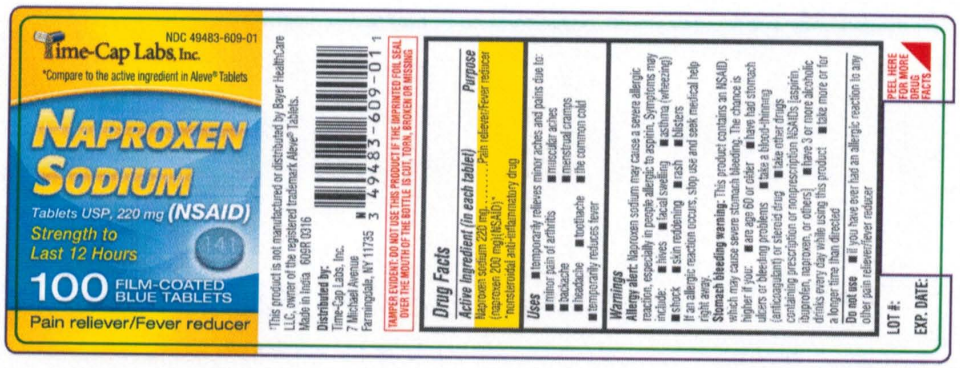
Pain reliever/ Fever reducer

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.



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