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

609R 49483-609 Naproxen Sodium Tablets 220 mg

DRUG FACTS

Active ingredient (in each tablet)
Naproxen sodium 220 mg
(naproxen 200 mg)
(NSAID)*
*nonsteroidal anti-inflammatory drug

Purposes
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: Ibuprofen 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, 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 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 the 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 right away (1-800-222-1222)

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 to12 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-to 12-hour period
- do not exceed 3 tablets in a 24-hour period

children under 12 years:

- ask a doctor

OTHER INFORMATION

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)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, FD&C Blue #2 Lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, titanium dioxide.

Questions or comments
call **1-877-290-4008**

Drug Facts (continued)

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 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 the 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

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Adhesive Area

This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Aleve®Tablets. Made in India 609H 0619

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

3 49483-609-01 1

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

Drug Facts

Active ingredient (in each tablet)	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:
● minor pain of arthritis ● muscular aches ● backache
● menstrual cramps ● headache ● toothache
● the common cold ■ temporarily reduces fever

Warnings

Allergy alert: Ibuprofen 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.
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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 ■ the stomach bleeding warning

Varnish Omit Area

PEEL HERE FOR MORE DRUG FACTS

LOT #:

EXP. DATE:

Time-Cap Labs, Inc.
NDC 49483-609-01

*Compare to the active ingredient in Aleve® Tablets

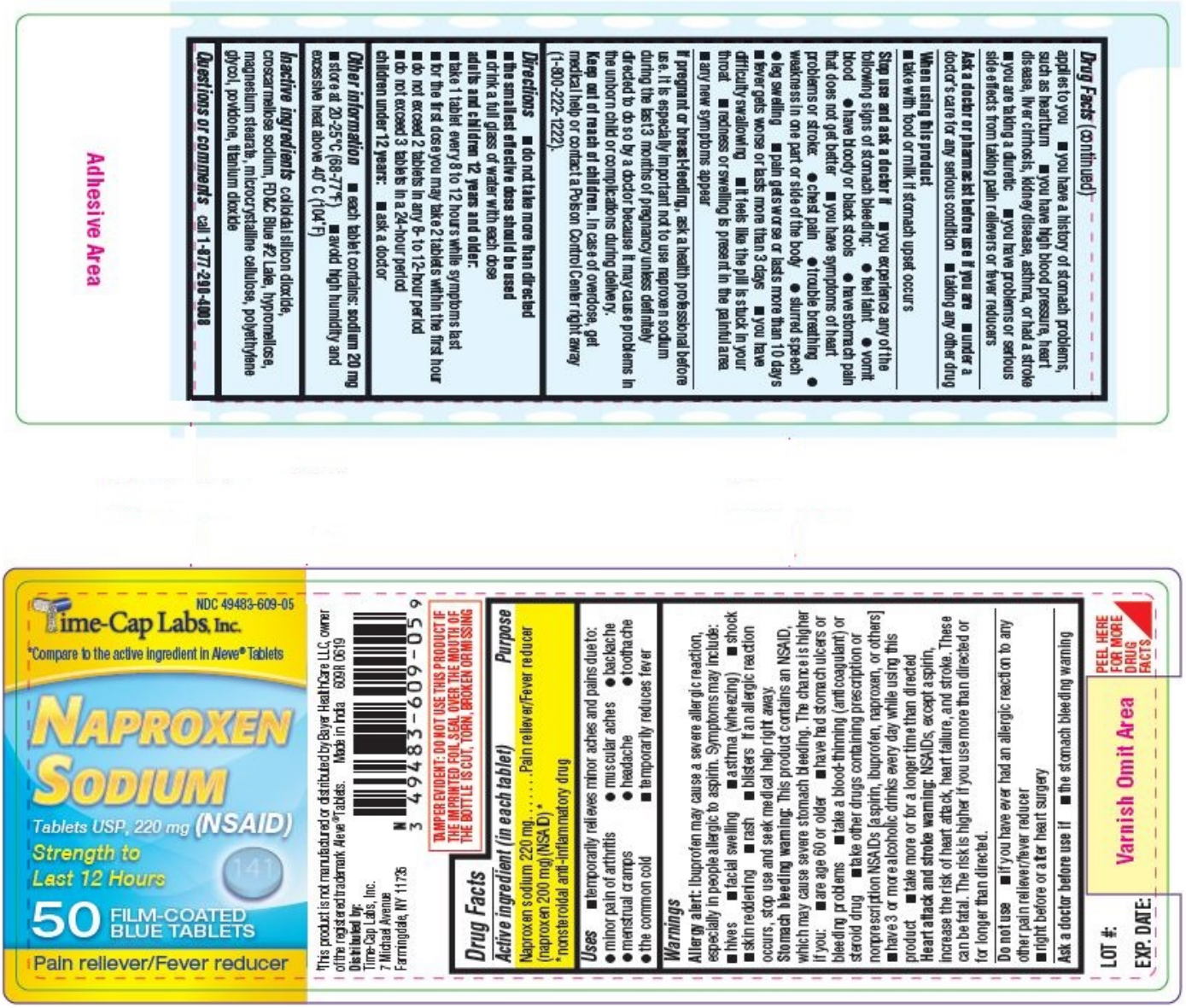
NAPROXEN SODIUM

Tablets USP, 220 mg (NSAID)

Strength to Last 12 Hours

100 FILM-COATED BLUE TABLETS

Pain reliever/Fever reducer



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 GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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: 12/2021 TIME CAP LABORATORIES, INC