

IBUPROFEN- ibuprofen capsule, liquid filled
TIME CAP LABORATORIES, INC

610-TCL

Solubilized Ibuprofen equal to
200 mg ibuprofen (NSAID)*

(present as the free acid and potassium salt)

* nonsteroidal anti-inflammatory drug

AMMONIA, FD&C GREEN #3, GELATIN, FERROSO FERRIC OXIDE, MEDIUM CHAIN TRIGLYCERIDES, POLYETHYLENE GLYCOL, PROPYLENE GLYCOL, POTASSIUM HYDROXIDE, WATER, SHELLAC, SORBITAN MONOOLEATE, SORBITAN

Directions

□ do not take more than directed

□

the smallest effective dose should be used

□

adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist

□

if pain or fever does not respond to 1 capsule, 2 capsules may be used

□

do not exceed 6 capsules in 24 hours, unless directed by a doctor

□ children under 12 years: ask a doctor

temporarily relieves minor aches and pain due to :

headache

toothache

backache

menstrual cramps

the common cold

muscular aches

minor pain of arthritis

temporarily reduces fever

PAIN RELIEVER/ FEVER REDUCER

Allergy alerts: 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.

IN CASE OF OVERDOSE, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY

NDC 49483-610-44

Time-Cap Labs, Inc.
 *Compare to the active ingredient in Advil® Liqui-Gels®

Ibuprofen

Capsules, 200 mg

SOFTGELS

Pain Reliever/
Fever Reducer (NSAID)

40 SOFTGELS
(Liquid Filled Capsules)

This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® Liqui-Gels®. MADE IN INDIA. 6107 1117. Manufactured by: Time-Cap Labs, Inc., 7 Macaulay Avenue, Farmingdale, NY 11735.

TAMPER EVIDENCE DO NOT OPEN UNTIL YOU HAVE BROKEN THE SEAL

OVER THE MOUTH OF THE CAPSULE. IF THE SEAL IS BROKEN OR MISSING.

3 49483-610-44 4

Active Ingredient (in each capsule)	Purpose
200 mg Ibuprofen (NSAID)*	Pain reliever/fever reducer (present as the free acid and potassium salt)

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains, due to:
 - headache
 - toothache
 - backache
 - menstrual cramps
- the common cold
- muscular aches
- minor pain of arthritis
- 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.

Warnings: Ibuprofen may increase the risk of bleeding. This product contains a non-steroidal anti-inflammatory drug (NSAID). NSAIDs may increase the risk of 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 beverages every day while taking 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

LOT #:

EXP. DATE:

PEEL HERE FOR MORE FACTS

Varnish Omit Area

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-610
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN (UNII: 2G86QN327L)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	133
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-610-44	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/23/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079205	12/23/2015	

Labeler - TIME CAP LABORATORIES, INC (037052099)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-610)

Revised: 12/2019

TIME CAP LABORATORIES, INC