IBUPROFEN- ibuprofen tablet, film coated
TIME CAP LABORATORIES,INC

Ibuprofen 200 mg (NSAID)* * nonstreoidal anti-inflammatory drug

Pain reliever / fever reducer

In case of overdose, get medical help or contact a PoisonControlCenter right away. (1-800-222-1222)

Close

colloidal silicon dioxide, croscamellose sodiium, FD&C yellow #6, magnesium stearate,microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium

do not take more than directed

the smallest effective dose should be used

do not take longer than 10 days, unless directed by a docter
(see Wanings)

adults and children 12 years and olderChildren under 12 years

take 1 tablet every 4 to 6 hours while symptoms persistif pain or fever does not respond to 1 tablet, 2 tablets may be used

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

ask a doctor

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

Allergy alerts: Ibuprofen may cause a severe allergy 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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 NSAID (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

IBUPROFEN TABLETS, USP ORANGE CAPSULE-SHAPED LABEL

IBUPROFEN TABLETS USP 200 MG ROUND ORANGE


NDC 49483-612-05
Time-Cap Labs, Inc.
†Compare to the active ingredient in Advil® Caplets
Ibuprofen
Caplets USP, 200 mg
CAPLETS
Pain Reliever/
Fever Reducer (NSAID)
120
50 FILM-COATED ORANGE CAPLETS
(Capsule-Shaped Tablets)
†This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® Caplets.
Made in India 612R0716
Distributed by:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735
3 49483-612-05 9
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 caplet) Purpose
Ibuprofen 200 mg (NSAID) ..... Pain reliever/Fever reducer
†nonsteroidal anti-inflammatory drug
Uses ■ temporarily relieves minor aches and pains due to:
■ backache ■ headache ■ menstrual cramps
■ minor pain of arthritis ■ muscular aches
■ the common cold ■ toothache
■ temporarily reduces fever
Warnings
Allergy alert: Ibuprofen 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 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
Do not use ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer
LOT #:
EXP. DATE:
Varnish
Omit Area
PEEL HERE FOR MORE DRUG FACTS

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49483-611
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	10mm
Flavor		**Imprint Code**	120
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49483-611-00	6500 in 1 BAG; Type 0: Not a Combination Product	11/16/2016	
2	NDC:49483-611-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2016	
3	NDC:49483-611-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091237	11/16/2016	

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49483-612
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	ROUND	**Size**	15mm
Flavor		**Imprint Code**	115
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49483-612-00	6500 in 1 BAG; Type 0: Not a Combination Product	11/16/2016	
2	NDC:49483-612-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2016	
3	NDC:49483-612-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091237	11/16/2016	

Labeler - TIME CAP LABORATORIES,INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-611, 49483-612)

Revised: 11/2016 TIME CAP LABORATORIES,INC