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

IBUPROFEN TABLETS USP 200MG ROUND BROWN

DRUG FACTS

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)*

* nonstreoidal anti-inflammatory drug

Purpose

Pain reliever / Fever reducer

Uses

temporarily relieves minor aches and pains due to:

- o headache
- o toothache
- o backache
- o menstrual cramps
- o the common cold
- o muscular aches
- o 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.

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 ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- 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

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- 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 problem 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 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 ibuprofen at 20 weeks or later in 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

adults and children 12 years and over:

- take 1 tablet every 4 to 6 hours while symptoms persist
- if 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

children under 12 years:

ask a doctor

OTHER INFORMATION

Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

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





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Drug Facts (continued)

Heart attack and stroke waming: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be tatal. 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

∎ stomach bleeding warning applies to you ■ you have problems or serious side effects from taking pain relievers or fever reducers

I you have a history of stomach problems, such as heartburn I you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke

you are taking a diuretic

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Stop use and ask a dodor if

you experience any of the following signs of stomach bleeding:

feel faint wormt blood whave bloody or black stools

lave 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 body

fever gets worse or lasts more than 3 days redness or swelling is present in the painful area any new symptoms appear ■ slurred speech ■ leg swelling pain gets worse or lasts more than 10 days

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Directions ■ do not take more than directed
the smallest effective dose should be used
■ adults and children 12 years and over take 1 tablet every 4 to 6
hours while symptoms persist

if pain or fever does not respond to 1 tablet, 2 tablets may be used o not exceed 6 tablets in 24 hours, unless directed by a doctor children under 12 years; ask a doctor

1/16" Margin

Other information
read all warnings and directions before use store at 20-25°C (68-77°F) sodium, iron oxide red, magnesium stearate, microcrystalline cellulose polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, nactive ingredients colloidal silicon dioxide, croscarmellose

Questions or comments? Call 1-877-290-4008

Adhesive Area

Inside



AMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL. OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSIN

Purpose Pain reliever/Fever reducer Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in If an allergic reaction occurs, stop use and seek medical help right away. Stomach bleeding warming: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you: ■ headsche ■ toothache ■ backache ■ merstrual cramps
■ the common cold ■ muscular aches ■ minor pain of arthritis
■ temporarily reduces fever Shock temporarily relieves minor aches and pains due to: people allergic to aspirin. Symptoms may include:

hives atacial swelling asthma (wheezing) rare age 60 or older have had stomach ulcers or bleeding problems Active ingredient (in each tablet) ■ blisters rash Orug Facts skin reddening

Drug Facts (continued under label

"This product is not manufactured or distributed by Haleon group of companies," lowner of the registered trademark Advil® Tablets

 have 3 or more alcoholic drinks every day while using this product
 take more or for a longer time than directed aspirin, ibuprofen, naproxen, or others]

take other drugs containing prescription or nonprescription NSAIDs

take a blood thinning (anticoagulant) or steroid drug

Made in India 601R 1123 Distributed by: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735

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Varnish Omit Area

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If pregnant or breast-teeding, ask a health professional before use, it is especially important not to use buproferen at 20 weeks or later in pregnancy unless of hirlarly directed to do so by a doctor because it may pregnancy before the unborn child or complications during delivery. Geep out of reach of children. In case of overdose, get medical help or contract a Polson Control Center right away (1-800-222-1222). ■ weakness in one part or side of the body ■ slurred speech ■ leg swelling ■ pain gets worse or lasts more than 10 days Ask a doctor or pharmaetst before use if you are under a doctor's care for any serious condition unable heart affector stroke, because buprofen may decrease this benefit of aspirin ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present in the painful area you have symptoms of heart problem or stroke: chest pain trouble breathing ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirmosis, kidney ■ stomach bleeding warning applies to you ■ you have problems or serious side effects from taking pain relievers Other information • read all warnings and directions 12 years and over: adults and children ■ the smallest effective dose should be used do not take more than directed any new symptoms appear you experience any of the following signs of stomach bleeding: Stop use and ask a doctor It When using this product ■ take with food or milk if stomach upset occurs you are taking a diuretic Ask a doctor before use If ■right before or after heart surgery ■ If you have ever had an allergic reaction to ibuprofe n or any other pain Do not use Drug Facts (continued) before use ■store at 20-25°C (68-77°F) :hlldren under 12 years: |■ ask a doctor taking any other drug Directions have bloody or black stools or fever reducers have stomach pain that does not get better feel faintvomit blood disease, asthma, or had a stroke reliever/rever reducer take 1 tablet every 4 to 6 hours while symptoms persist if 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

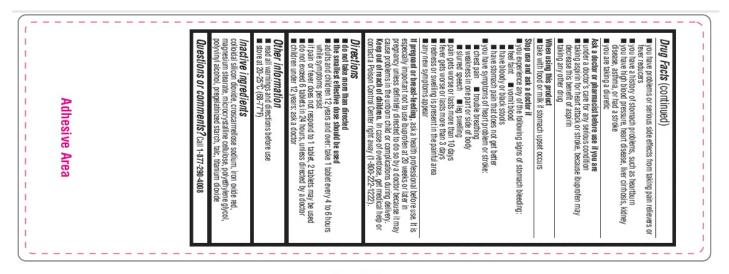
Inside

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl abohol, pregledinized starch, alt., titarium dioxide

luestions or comments? call 1-877-290-4008

Adhesive Area



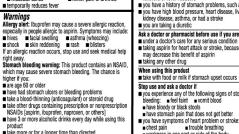


Inside





Drug Facts (continued) Drug Facts (continued) Drug Facts directed or for longer than dire Active ingredient (in each tablet) Purpose but not use if you have ever had an allergic reaction to ibuprofen or any other pain reliever/lever reducer right before or after heart surgery Uses ■ right before or after heart surgery Ack a doutor before use if ■ stomach bleeding warning applies to you ■ you have probleme or serious side effects from taking pain relievers or fever reducers you have a polition of stomach problems, such as hearthum ■ you have a history of stomach problems, such as hearthum ■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke ■ you are taking a diuretic we memograrily relieves minor aches and pains due to: In headache tothache backache In mestural cramps the common cold In muscular aches In morpain of arthritis In temporarily reduces fever Directions



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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

■ redness or swelling is present in the pai ■ any new symptoms appear

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Other information
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Questions or comments? call 1-877-290-4008



Time-Cap Labs, Inc. 7 Michael Avenue

Made in India Distributed by: Time-Cap Farmingdale, NY 11735 40138201 Code No.: GOLDRUG

Varnish Omit Area

Exp Date:

IBUPROFEN

ibuprofen tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-114	
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		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
TALC (UNII: 7SEV7J4R1U)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
STARCH, CORN (UNII: O8232NY3SJ)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			

Product Characteristics				
Color	brown	Score	no score	
Shape	ROUND (Biconvex)	Size	10mm	
Flavor		Imprint Code	114	
Contains				

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49483-114- 50	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2021		
2	NDC:49483-114- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/09/2021		
3	NDC:49483-114- 17	200 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2023		
4	NDC:49483-114- 73	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2023		

Marketing Information			
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date			
ANDA	ANDA091239	03/22/2016	

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49483-601

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		
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POLYVINYL ALCOHOL (UNII: 532B59J990)			
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			

Product Characteristics				
Color	brown	Score	2 pieces	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	114	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49483-601- 00	6500 in 1 BAG; Type 0: Not a Combination Product	03/22/2016		
2	NDC:49483-601- 05	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016		
3	NDC:49483-601- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016		
4	NDC:49483-601- 50	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016	08/07/2021	
5	NDC:49483-601- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016	08/07/2021	

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
ANDA	ANDA091239	03/22/2016		

IBUPROFEN

ibupfrofen tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-600	
Route of Administration	ORAL			

I	Active Ingredient/Active Moiety					
l	Ingredient Name	Basis of Strength	Strength			
l	IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg			

Inactive Ingredients					
Ingredient Name	Strength				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)					
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)					
FERRIC OXIDE RED (UNII: 1K09F3G675)					
MAGNESIUM STEARATE (UNII: 70097M6I30)					
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)					
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)					
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)					
POLYVINYL ALCOHOL (UNII: 532B59J990)					
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)					
TALC (UNII: 7SEV7J4R1U)					

Product Characteristics				
Color	brown	Score	2 pieces	
Shape	CAPSULE	Size	15mm	
Flavor		Imprint Code	117	
Contains				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49483-600- 05	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016			
2	NDC:49483-600- 01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016			

ANDA				
ANDA	ANDA091239	03/22/2016		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Marketing Information				
3 50	500 in 1 BOTTLE; Type 0: Not a Combination Product 11/14/2017			

Labeler - TIME CAP LABORATORIES,INC (037052099)

Registrant - TIME CAP LABORATORIES,INC (037052099)

Establishment				
Name	Address	ID/FEI	Business Operations	
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-601, 49483-600, 49483-114)	

Revised: 11/2023 TIME CAP LABORATORIES,INC