

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

601R -TCL IBUPROFEN 200MG ROUND

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

Pain reliever / fever reducer

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

Close

colloidal silicon dioxide, croscarmellose sodium, iron oxide red, 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 doctor
(see Warnings)

adults and children 12 years and older Children under 12 years

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.

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 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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause 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 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.

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.

Time-Cap Labs, Inc.
NDC 49483-600-05
*Compare to the active ingredient in Advil® Caplets.

Ibuprofen

Tablets USP, 200 mg

CAPLETS
Pain Reliever/
Fever Reducer (NSAID)

50 FILM-COATED
BROWN 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 6009 0617
Distributed by:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735
N 49483-600-05 6
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
 - minor pain of arthritis
 - 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:

- asthma (wheezing)
- hives
- swelling of the face, lips, tongue, or throat
- difficulty breathing

If an allergic reaction occurs, stop use and seek medical help.

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 other drugs containing prescription or nonprescription NSAIDs, aspirin, ibuprofen, naproxen, or others
- take other drugs containing prescription or nonprescription blood thinners

Always use with care. Every day using this product may increase your risk of stomach bleeding.

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.

LOT #: _____
EXP. DATE: _____
PEEL HERE TO REVEAL
Varnish Omit Area
DRUG FACTS

Time-Cap Labs, Inc. NDC 49483-600-01
*Compare to the active ingredient in Advil® Caplets.

Ibuprofen

Tablets USP, 200 mg

CAPLETS

Pain Reliever/
Fever Reducer (NSAID)

100 FILM-COATED
BROWN 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 800R 0617
Distributed by:
Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735



DANGER: DO NOT USE THIS PRODUCT IF THE UNPRINTED SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.

Drug Facts

Active Ingredient (in each caplet)
Ibuprofen 200 mg (NSAID) Pain reliever/fever reducer
nonsteroidal anti-inflammatory drug

Uses ■ temporarily relieves minor aches and pains due to:
■ headache ■ headache ■ menstrual cramps
■ minor pain or 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) ■ hives ■ facial swelling
■ rash ■ skin redness ■ blisters ■ If an allergic reaction
occurs, stop using this product and seek medical help right away.
Stomach bleeding warning: This product can cause stomach bleeding, 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
Heart attack and stroke warning: This product may 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.

LOT #: _____
EXP. DATE _____

PEEL HERE TO REVEAL MORE DRUG FACTS

Time-Cap Labs, Inc. NDC 49483-600-50
*Compare to the active ingredient in Advil® Caplets.

Ibuprofen

Tablets USP, 200 mg

CAPLETS

Pain Reliever/
Fever Reducer (NSAID)

THIS PACKAGE FOR
HOUSEHOLDS WITHOUT
YOUNG CHILDREN

500 FILM-COATED
BROWN CAPLETS
(Capsule-Shaped Tablets)

This product is not manufactured or distributed by Pfizer Consumer
Pharmaceuticals, Inc. or its subsidiaries. It is a registered trademark of Advil® Caplets.
Made in India 6BR 0617
Distributed by:
Time-Cap Labs, Inc.
7 Michael Avenue
Paramus, NY 11775



Drug Facts

Active ingredient (in each caplet)
Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Uses

- Temporarily relieves minor aches and pains due to:
 - backache
 - headache
 - muscular aches
 - minor pain of arthritis
 - 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
- swelling of the face, lips, tongue, or throat
- difficulty breathing

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 NSAID.
- If you are taking aspirin, salicylates, or other NSAIDs.
- If you have had stomach or intestinal bleeding, ulcers, or perforation of the stomach or intestine.
- If you have had kidney disease.
- If you are taking blood thinners, anticoagulants, or antiplatelet drugs.
- If you are taking other NSAIDs, including over-the-counter NSAIDs.
- If you are taking other drugs containing prescription or over-the-counter NSAIDs (aspirin, ibuprofen, naproxen, or others).
- If you are taking a diuretic (water pill).
- If you are taking a beta-blocker (heart medicine).
- If you are taking a calcium channel blocker (heart medicine).
- If you are taking a corticosteroid (steroid).
- If you are taking a diuretic (water pill).
- If you are taking a beta-blocker (heart medicine).
- If you are taking a calcium channel blocker (heart medicine).
- If you are taking a corticosteroid (steroid).

Keep out of reach of children. See important information about this medicine on page 2 of the package insert.

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ROLL
ALOP
DOT
to see
actual
label

Time-Cap Labs, Inc. NDC 49483-601-05
*Compare to the active ingredient in Advil® Tablets.

Ibuprofen

Tablets USP, 200 mg

TABLETS

Pain Reliever/
Fever Reducer (NSAID)

50 FILM-COATED
BROWN TABLETS

This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil® Tablets. Made in India. 501R 0917

Time-Cap Labs, Inc.
7 Michael Avenue
Farmingdale, NY 11735

3 49483-601-053

THIS PRODUCT IS NOT TO BE USED IF THE BOTTLE IS DIRT, TORN, BROKEN OR MISSING

Drug Facts

Active Ingredient (in each tablet)
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) ■ hives ■ facial swelling ■ itchy
■ rash ■ shock ■ skin redness 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 65 or older
■ 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 ■ you have problems or serious

LOT #:

EXP. DATE:

PEEL HERE FOR MORE DRUG FACTS

NDC 49483-601-01

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

Ibuprofen

Tablets USP, 200 mg

TABLETS

Pain Reliever/
Fever Reducer **(NSAID)**

114

100 FILM-COATED
BROWN TABLETS

This product is not manufactured or distributed by Pfizer Consumer Healthcare, Division of registered trademark Advil® Tablets. Made in India. 03/11/97/17
 Distributed by:
 Time-Cap Labs, Inc.
 7 Michael Avenue
 Farmingdale, NY 11735

3 49483-601-01 5
 THE INFORMATION ON THIS PRODUCT IS THE PROPERTY OF TIME-CAP LABS, INC. IF THE BOTTLE IS COIL, TORN, BROKEN OR MISSING.

Drug Facts

Active Ingredient (in each tablet)
 Ibuprofen 200 mg (NSAID) Pain reliever/fever reducer
 *nonsteroidal anti-inflammatory drug

Purpose
 Ibuprofen 200 mg (NSAID) Pain reliever/fever reducer

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)
- hives
- rash
- shock
- skin redness
- facial swelling
- throat swelling
- difficulty breathing

Stop use and seek medical help right away, if you have had stomach ulcers or bleeding problems

Warnings:

- 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:

- you have problems or serious

LOT #:
 EXP. DATE: Varnish Omit Area

PEEL HERE FOR MORE DRUG FACTS

Time-Cap Labs, Inc. NDC 49483-601-50
*Compare to the active ingredient in Advil® Tablets.

Ibuprofen

Tablets USP, 200 mg

TABLETS

Pain Reliever/
Fever Reducer (NSAID)

THIS PACKAGE FOR
HOUSEHOLDS WITHOUT
YOUNG CHILDREN

500 FILM-COATED
BROWN TABLETS

This product is not manufactured or distributed by Pfizer Consumer Health, the original manufacturer of Advil® Tablets.

Made in India 601R 0617

Distributed by:

Time-Cap Labs, Inc.

7 Michael Avenue

Farmingdale, NY 11735



Drug Facts

Active Ingredient (in each tablet)

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

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 also taking aspirin, other NSAIDs, or blood thinners
- take a blood-thinning (anticoagulant) or steroid (corticosteroid) drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

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

- you have problems or serious side effects from taking pain relievers or fever reducers

LOT #:

EXP. DATE:

SEEK HELP
FOR MORE
DRUG
FACTS

Varnish Omit Area

NDC 49483-601-10

Time-Cap Labs, Inc.

Compare to the active ingredient in Advil® Tablets.

Ibuprofen

Tablets USP, 200 mg

TABLETS

Pain Reliever/
Fever Reducer (NSAID)

THIS PACKAGE FOR
HOUSEHOLDS WITHOUT
YOUNG CHILDREN

Actual Size

1000 FILM-COATED
BROWN TABLETS

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
Ibuprofen 200 mg (NSAID) Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - muscle cramps
 - minor pain of arthritis
 - the common cold
 - throatache
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives (wheals)
- swelling of the face, lips, tongue, or throat
- difficulty breathing

 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 aspirin, aspirin-containing prescription or nonprescription NSAIDs, or aspirin-containing over-the-counter pain relief product
- 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.

Drug Facts (continued)

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

Ask a doctor before use if

- 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

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit in 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:
 - black or tarry stools
 - blood in vomit or stool
 - have bloody or black stools
- you 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

Drug Facts (continued)

Do not give worse or take more than 10 days

- fever lasts longer than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breastfeeding, ask a health professional before use. It is especially important not to use ibuprofen 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
- 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
- ask a doctor

Other information

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

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

Questions or comments? call 1-877-291-4008



Varnish Omit Area

LOT #
EXP. DATE:

This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil®. Manufactured by Time-Cap Labs, Inc., 7 Michael Avenue, Farmingdale, NY 11735. ©2019

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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
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)	

Product Characteristics

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

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	
5	NDC:49483-601-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2016	

Marketing Information

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

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49483-600
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
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)	

Product Characteristics

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

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	
3	NDC:49483-600-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/14/2017	

Marketing Information

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

Labeler - TIME CAP LABORATORIES,INC (037052099)

Establishment

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

Revised: 9/2019

TIME CAP LABORATORIES,INC