IBUPROFEN- ibuprofen tablet, coated
TARGET CORPORATION

601R TARGET - IBUPROFEN 200 MG TABLETS 11673-991

ACTIVE INGREDIENT(S)

Ibuprofen 200 mg (NSAID)*

* nonstreoidal anti-inflammatory drug

INACTIVE INGREDIENTS

Silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide.

PURPOSE

Pain reliever / fever reducer

USE(S)

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

DIRECTIONS

do not take more than directed
the smallest effective dose should be used

adults and children 12 years and older

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

KEEP OUT OF REACH OF CHILDREN

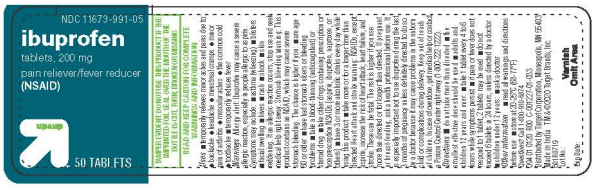
In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222

WARNINGS

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.



NDC 11673-991-01

ibuprofen

tablets, 200 mg

pain reliever/fever reducer

(NSAID)

100 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

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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 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. If pregnant or breast-feeding, 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 ■ 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 ■ read all warnings and directions before use ■ store at 20-25°C (68-77°F)

***Questions?* Call 1-800-910-6874**

094 01 0122 R00 C-001227-01-033

Dist. by Target Corporation, Mpls., MN 55403

Made in India

601R 0719

Lot No.:

Exp Date:

Varnish Omit Area

NDC 11673-991-20

ibuprofen

tablets, 200 mg

pain reliever/fever reducer
(NSAID)

200 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

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

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.

If pregnant or breast-feeding, 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**

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

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

Questions? **Call 1-800-910-6874**

094 01 0026 R00 C-001227-01-033

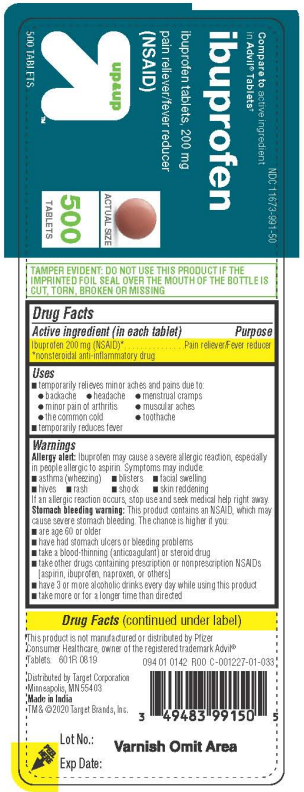
Distributed by Target Corporation, Minneapolis, MN 55403

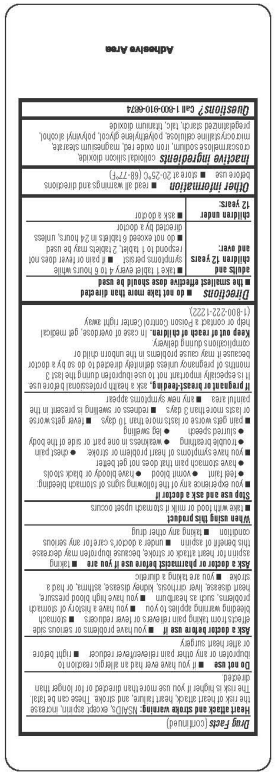
Made in India

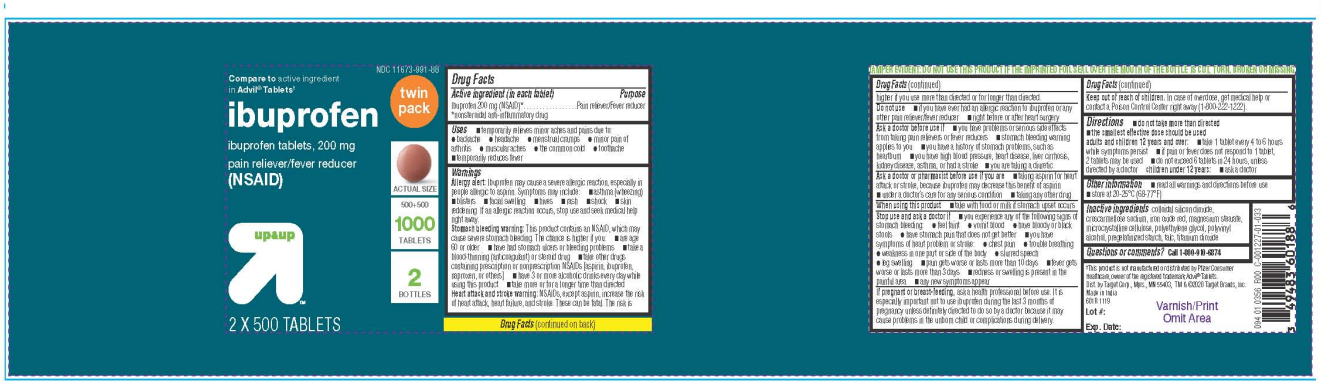
601R 0719

Lot No.:
Exp. Date:

Varnish Omit Area


Compare to active ingredient in Advil® Tablets*
ibuprofen
ibuprofen tablets, 200 mg
pain reliever/fever reducer
(NSAID)
NDC 11673-981-50
500 TABLETS
up&up
500
TABLETS
ACTUAL SIZE
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:
● 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
Drug Facts (continued under label)
This product is not manufactured or distributed by Pfizer
Consumer Healthcare, owner of the registered trademark Advil®
Tablets: 601R:0819
094 01 0142 R00 C-001227-01-033
Distributed by Target Corporation
Minneapolis, MN 55403
Made in India
TM & ©2020 Target Brands, Inc.
3 49483 99150 5
Lot No.:
Exp Date:
Varnish Omit Area


Adhesive Area
Drug Facts (continued)
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 ibuprofen 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 ■ 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
Ask a doctor or pharmacist before use if you are taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ 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 problem or stroke ● chest pain ● trouble breathing ● weakness in one part or side of the body
■ 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 breastfeeding, ask a health professional before use because it may cause problems in the unborn child or complications during delivery
If it is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor
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 ■ read all warnings and directions ■ 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? Call 1-800-910-6874



IBUPROFEN

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11673-991
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-991-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2020	
2	NDC:11673-991-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2020	
3	NDC:11673-991-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2020	
4	NDC:11673-991-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2020	
5	NDC:11673-991-88	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	02/04/2020	

Labeler - TARGET CORPORATION (006961700)

Registrant - TIME CAP LABORATORIES INC (037005209)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11673-991)

Revised: 5/2020 TARGET CORPORATION