

IBUPROFEN- ibuprofen tablet, coated
TARGET CORPORATION

612R TARGET- IBUPROFEN CAPLETS 200 MG ORANGE NDC 11673-993

Ibuprofen 200 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

Silicon dioxide, croscarmellose sodium, FD & C yellow # 6 aluminum lake, 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 caplet every 4 to 6 hours while symptoms persist
if pain or fever does not respond to 1 caplet, 2 caplets may be used
do not exceed 6 caplets 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 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: NSAID's except aspirin, increases 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.

Varnish/Print
Omit Ate



Lot No.: 094 01 0696
Exp Date: 09/2019

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Top of Package

Read all product information before using.
Keep the box for important information.

Drug Facts

Active ingredient (in each caplet): Purpose
Ibuprofen 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 ■ rash

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 over-the-counter
NSAIDs (aspirin, ibuprofen, rofecoxib, 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)

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 ■ stomach bleeding
warning applies to you ■ you have a history of
stomach problems, such as heartburn
■ you have high blood pressure, heart disease,
liver or 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 ● leaf faint ● vomit blood
● have bloody or black stools
● have stomach pain that does not get better

Bottom of Package

Drug Facts (continued)

■ 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 3 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 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 caplet every 4 to 6 hours while symptoms persist
■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years: ■ ask a doctor

Other information ■ read all warnings and

Varnish
Omit

NDC 11673-993-01
Compare to the active ingredient
in Motrin® IB Caplets.*

Ibuprofen

Ibuprofen Caplets, 200 mg
Pain Reliever / Fever Reducer (NSAID)



ACTUAL SIZE

100 CAPLETS**
(*CAPSULE-SHAPED TABLETS)

Varnish/Print Omit Area

E826R

Varnish
Omit

Contains aspirin. Avoid taking any other drug containing aspirin while using this product. See the important information on the inside of the box.

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).

Do not use if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer.

Do not use if you are taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin.

Do not use if you are under a doctor's care for any serious condition or taking any other drug.

Do not use if you are pregnant or breast-feeding, unless directed by a health professional.

Do not use if you are taking ibuprofen during the last 3 months of pregnancy unless directed to do so by a doctor.

Do not use if you are taking ibuprofen while breastfeeding.

Do not use if you are taking ibuprofen while driving or operating machinery.

Do not use if you are taking ibuprofen while drinking alcohol.

Do not use if you are taking ibuprofen while taking other NSAIDs.

Do not use if you are taking ibuprofen while taking blood thinners.

Do not use if you are taking ibuprofen while taking diuretics.

Do not use if you are taking ibuprofen while taking aspirin.

Do not use if you are taking ibuprofen while taking acetaminophen.

Do not use if you are taking ibuprofen while taking naproxen.

Do not use if you are taking ibuprofen while taking celecoxib.

Do not use if you are taking ibuprofen while taking rofecoxib.

Do not use if you are taking ibuprofen while taking valdecoxib.

Do not use if you are taking ibuprofen while taking etoricoxib.

Do not use if you are taking ibuprofen while taking salsalicylic acid.

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NDC 11673-993-26

Compare to the active ingredient
in Motrin® IB Caplets.†

Ibuprofen

Ibuprofen Caplets, 200 mg
Pain Reliever / Fever Reducer
(NSAID)



Actual Size

225 CAPLETS**

(** CAPSULE-SHAPED TABLETS)

Package Not Child-Resistant

Drug Facts

Active ingredient (in each caplet): Ibuprofen (NSAID) Pain reliever/fever reducer

Purpose: To temporarily relieve minor aches and pains due to:

- toothaches
- menstrual cramps
- minor pain of arthritis
- muscle aches
- 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
- rash
- shock
- dizziness
- facial swelling

Stop use if you experience any of these symptoms. See your doctor as soon as possible. Do not use if you have ever had a severe allergic reaction to aspirin or other NSAIDs. See your doctor as soon as possible if you have ever had a severe allergic reaction to aspirin or other NSAIDs. The chance is higher if you have ever had a severe allergic reaction to aspirin or other NSAIDs.

Use: Take 1 or 2 caplets every 4 to 6 hours as needed. Do not take more than 6 caplets in 24 hours, unless directed by a doctor.

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.

Drug Facts (continued under label)

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., Medical Consumer Healthcare Division, owner of the registered trademark Motrin®.

†See your doctor as soon as possible if you have ever had a severe allergic reaction to aspirin or other NSAIDs.

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Lot No. _____ Exp. Date: _____



80% IPR

Varnish Omit Area

Drug Facts (continued)

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 a history of ulcers ■ you are on blood-thinning drugs ■ you have kidney or liver problems ■ you are pregnant or breastfeeding ■ you have ever had a stroke ■ you are taking aspirin for heart failure or stroke because ibuprofen may decrease the benefit of aspirin ■ under a doctor's care for any serious condition ■ taking any other drug

When using this product: ■ eat 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: ● heartburn ● 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 ● egg swelling ■ pain gets worse or lasts more than 10 days ● have gits worse or lasts more than 5 days ● weakness or swelling is present in the painful area ■ any new symptoms appear

Request a heart-healthy diet: Get a health professional before use. Dependently dependent to use ibuprofen during the last 3 months of pregnancy unless specifically 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. (1-800-272-1222)

Directions: ■ Do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: ● take 1 caplet every 4 to 6 hours while symptoms persist ● if pain or fever does not respond to 1 caplet, 2 caplets may be used ● do not exceed 6 caplets 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)

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, FD&C yellow #6 aluminum lake, hydroxypropyl methylcellulose, hydroxypropyl methylcellulose, iron oxide black, iron oxide yellow, polyethylene glycol, polyethylene glycol, polyethylene glycol, titanium dioxide, croscarmellose sodium, docusate calcium

Questions? Call 1-800-914-8874

Adhesive Area

ibuprofen tablet, coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11673-993 |
| 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 |
|---|-----------------|
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| 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) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

Product Characteristics

| | | | |
|-----------------|--------------------|---------------------|----------|
| Color | orange | Score | no score |
| Shape | CAPSULE ((CAPLET)) | Size | 10mm |
| Flavor | | Imprint Code | 120 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:11673-993-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 01/01/2020 | |
| 2 | NDC:11673-993-26 | 225 in 1 BOTTLE; Type 0: Not a Combination Product | 01/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| ANDA | ANDA091237 | 01/01/2020 | |

Labeler - TARGET CORPORATION (006961700)

Registrant - TIME CAP LABORATORIES INC (037052099)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------|----------------|---------------|----------------------------|
| MARKSANS PHARMA LTD | | 925822975 | manufacture(11673-993) |

Revised: 5/2020

TARGET CORPORATION