UP AND UP IBUPROFEN- ibuprofen tablet, film coated Target Corporation

Target Corporation Ibuprofen Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- 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 chances are 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

- you have problems or serious side effects from taking pain relievers or fever reducers
- the 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 problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of 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 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 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

Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

Questions?

Call 1-888-547-7400

Package/Label Principal Display Panel

see new warnings Compare to active ingredient in Advil® Ibuprofen Tablets ibuprofen tablets 200 mg pain reliver/fever reducer (NSAID) PACKAGE NOT CHILD-RESISTANT ACTUAL SIZE 500 TABLETS 500TABLETS



UP AND UP IBUPROFEN ibuprofen tablet, film coated **Product Information Product Type** HUMAN OTC DRUG NDC:11673-314 Item Code (Source) **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 DIO XIDE (UNII: ETJ7Z6 XBU4) STARCH, CORN (UNII: O8232NY3SJ) CROSCARMELLOSE SODIUM (UNII: M280L1HH48) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) STEARIC ACID (UNII: 4ELV7Z65AP) TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) POLYSORBATE 80 (UNII: 6OZP39ZG8H) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) FERRIC OXIDE RED (UNII: 1K09F3G675) FERRIC OXIDE YELLOW (UNII: EX438O2MRT) **Product Characteristics** Color BROWN Score no score Shape ROUND Size 10 mm Flavor Imprint Code 12 Contains Packaging # Item Code **Package Description** Marketing Start Date Marketing End Date 1 NDC:11673-314-90 500 in 1 BOTTLE; Type 0: Not a Combination Product 03/13/2020 **Marketing Information** Marketing Category **Application Number or Monograph Citation** Marketing Start Date Marketing End Date ANDA ANDA072096 03/13/2020

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Target Corporation