

IBUPROFEN - ibuprofen tablet, coated
Velocity Pharma

Ibuprofen Tablets, USP 200mg

Active Ingredient

(in each tablet)

Ibuprofen 200 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

Purpose

pain reliever/fever reducer

Uses

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

Warnings

Allergy alert: This product may cause a severe allergic reaction, especially in people allergic to aspirin, symptoms may include

- hives
- facial swelling
- asthma(wheezing)
- shock
- skin reddning
- 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.

do not use

- this product if you have ever had an allergic reaction to any pain reliever/fever reducer
- right before or after heart surgery

ask your 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 or asthma

ask your 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 the benefit of aspirin
- taking any other drug

when using this product

- take with food or milk
- The risk of heart attack or stroke may increase if you are more than directed or for longer than directed

Stop use and ask a doctor if:

- you experience and of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- 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 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.

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 persists.
- 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. keep carton
- store at 20-25 °C (68-77 °F)
- avoid excessive heat above 40°C (104°F)

- do not use if imprinted safety seal under the cap is broken or missing

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 toll free 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Drug Facts (continued)

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Questions or comments?

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COMPARE TO
ACTIVE INGREDIENT OF
ADVIL[®]

NDC 76168-012-08



Ibuprofen

Tablets USP, 200 mg
PAIN RELIEVER • FEVER REDUCER (NSAID)
40 Brown Coated Tablets



ASSURED
Ibuprofen
Tablets USP, 200 mg EACH
PAIN RELIEVER • FEVER REDUCER (NSAID)
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.
40 Brown Coated Tablets
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Active ingredients in each tablet

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

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Pain reliever/fever reducer

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 - minor pain of arthritis
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- take more or for a longer time than directed.

ASSIBUC

Distributed by:
Greenbrier International, Inc.
Chesapeake, VA 23320 133152



C528A

NDC 76168-012-08



Ibuprofen

Tablets USP, 200 mg EACH
PAIN RELIEVER • FEVER REDUCER (NSAID)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

40 Brown Coated Tablets

Uses ■ temporarily relieves minor aches and pains due to: headache, muscular aches, menstrual cramps, the common cold, backache, toothache, minor pain of arthritis.
■ temporarily reduces fever

Warnings
■ **Ask your doctor before use** if you are pregnant, under a doctor's care for a serious condition, age 60 or over, taking any other drug or have stomach problems.
■ This product 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. **Do not use** this product if you have ever had an allergic reaction to any pain reliever/ fever reducer. ■ This product contains a nonsteroidal anti-inflammatory drug (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. ■ The risk of heart attack or stroke may increase if you use more than directed or for longer than directed.

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READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Distributed by: Greenbrier International, Inc.
Chesapeake, VA 23320 **133152**
Lot No:
Exp. Date: ASSIBUL

IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76168-012
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	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)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
POLYVINYL ALCOHOL (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:76168-012-08	40 in 1 BOTTLE		
1		1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	07/01/2012	

Labeler - Velocity Pharma (962198409)

