

IBUPROFEN- ibuprofen tablet, coated
TOPCO ASSOCIATES LLC

1111C-TCR-2022-1118

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 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)
- avoid high humidity and excessive heat above 40°C (104°F)
- retain carton for complete product information and warnings

Inactive ingredients

colloidal silicon dioxide, corn starch, FD&C yellow #6, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

TopCare® Health

COMPARE TO MOTRIN® IB ACTIVE INGREDIENT†

NDC 36800-286-03

Ibuprofen

Tablets, 200 mg

PAIN RELIEVER • FEVER REDUCER (NSAID)

100 COATED TABLETS

actual size

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING



F111C03TCR_R0

†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Motrin® IB.

**DO NOT USE IF IMPRINTED SEAL
UNDER CAP IS BROKEN OR MISSING**

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* nonsteroidal anti-inflammatory drug

- Uses**
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Drug Facts (continued)

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Drug Facts (continued)

Inactive ingredients (continued)
caldiol silicium dioxide, corn starch, FD&C yellow #6, polyethylene glycol, polyvinyl alcohol, povidone, stearic acid, talc, titanium dioxide

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Drug Facts (continued)

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COMPARE TO MOTRIN® IB ACTIVE INGREDIENT



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

100 COATED TABLETS

COATING FREE AREA

IBUPROFEN
ibuprofen tablet, coated

Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)
Route of Administration	ORAL	NDC:36800-286

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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-286-03	1 in 1 CARTON	11/01/2021	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202312	11/01/2021	

Labeler - TOPCO ASSOCIATES LLC (006935977)