

IBUPROFEN- ibuprofen tablet
TOPCO ASSOCIATES LLC

Ibuprofen
Tablets USP, 200 mg
PAIN RELIEVER / FEVER REDUCER
(NSAID)*

Contains no ingredient made from a gluten-containing grain (wheat, barley or rye)

Active ingredient (in each caplet)

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

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 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.

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 at 20 weeks or later in 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 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

- store between 20-25°C (68-77°F)
- do not use if foil inner seal is broken or missing**

Inactive ingredients

colloidal silicon dioxide, FD&C yellow #6, maize starch, polyethylene glycol, polyvinyl alcohol, povidone k30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST

Principal Display Panel

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL (Capsule shaped tablet)	Size	14mm
Flavor		Imprint Code	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-662-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202312	10/14/2024	

Labeler - TOPCO ASSOCIATES LLC (006935977)

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TOPCO ASSOCIATES LLC