

IBUPROFEN- ibuprofen tablet
Trifecta Pharmaceuticals USA LLC

Ibuprofen Tablets 200mg

Active Ingredient (in each tablet)

Ibuprofen, 200mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever / Fever Reducer

nonsteroidal anti-inflammatory drug

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

Uses

Temporarily relieves minor aches and pains due to

- Common cold
- headache
- minor pain of arthritis
- toothache
- backache
- muscular aches
- menstrual cramps

temporarily reduces fever

Warnings

Allergy alert

Ibuprofen may cause severe allergic reactions, 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 a NSAID, which may cause severe stomach bleeding. The chances are higher if you:

- are age 60 or older
- have stomach ulcers or bleeding problems
- take 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 or 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.

Contains FD+C Yellow No. 5 (tartrazine) as a color additive

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 the benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

Keep out of reach of children

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 4-6 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 of age

- Ask a doctor

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.

Other Information

- Store at 20°C - 25°C (68°F - 77°F)
- Do not use if printed packet is torn or punctured.

TAMPER EVIDENT child resistant packets. Do not use any opened or torn packets.

Inactive Ingredients

Colloidal Silicon Dioxide, Croscarmellose Sodium, FD&C Blue #2, FD&C Yellow #5, FD&C Yellow #6, Iron Oxide Red, Lecithin, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Pregelatinized Starch, Talc, Titanium Dioxide

Questions or Comments?

Call 1-888-296-9067

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP BOX FOR COMPLETE WARNINGS AND INFORMATION.

When using this product

Take with food or milk if stomach upset occurs

Distributed By:

Distributed By:

Trifecta Pharmaceuticals USA®

Ft. Lauderdale, FL. 33301 USA

1-888-296-9067

*This product is not manufactured or distributed by Pfizer, owner of the registered trademark Advil®

Reorder No. 2022

Made in the USA

OUTSIDE BOX



INNER PACKET



IBUPROFEN

ibuprofen tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-141
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
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	BI06
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-141-01	50 in 1 BOX	08/08/2023	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69396-141-05	10000 in 1 BAG	08/08/2023	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207095	08/08/2023	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 2/2024

Trifecta Pharmaceuticals USA LLC