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

☐ temporarily relieves minor aches and pains due to:☐ headache ☐ muscular aches ☐ minor pain of arthritis

 \square toothache \square backache \square the common cold \square menstrual cramps

Purposes

Pain reliever/ fever reducer

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temporarily reduces fever	
Allergy alert:	
Ibuprofen may cause a severe allergic reaction, especially in people allerg 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
$\hfill \square$ 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
$\ \square$ 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
$\hfill\square$ 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 fi 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

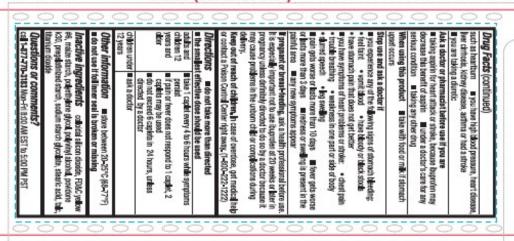
Questions or comments?

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

Principal Display Panel



Inside (adhesive side)



IBUPROFEN

ibuprofen tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-662

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

mactive ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
POVIDONE K30 (UNII: U725QWY32X)			
STEARIC ACID (UNII: 4ELV7Z 65AP)			

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: 08232NY3SJ)	
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 I	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)

Revised: 10/2024 TOPCO ASSOCIATES LLC