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 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]

 avoid excessive heat above 40°C (104°F)

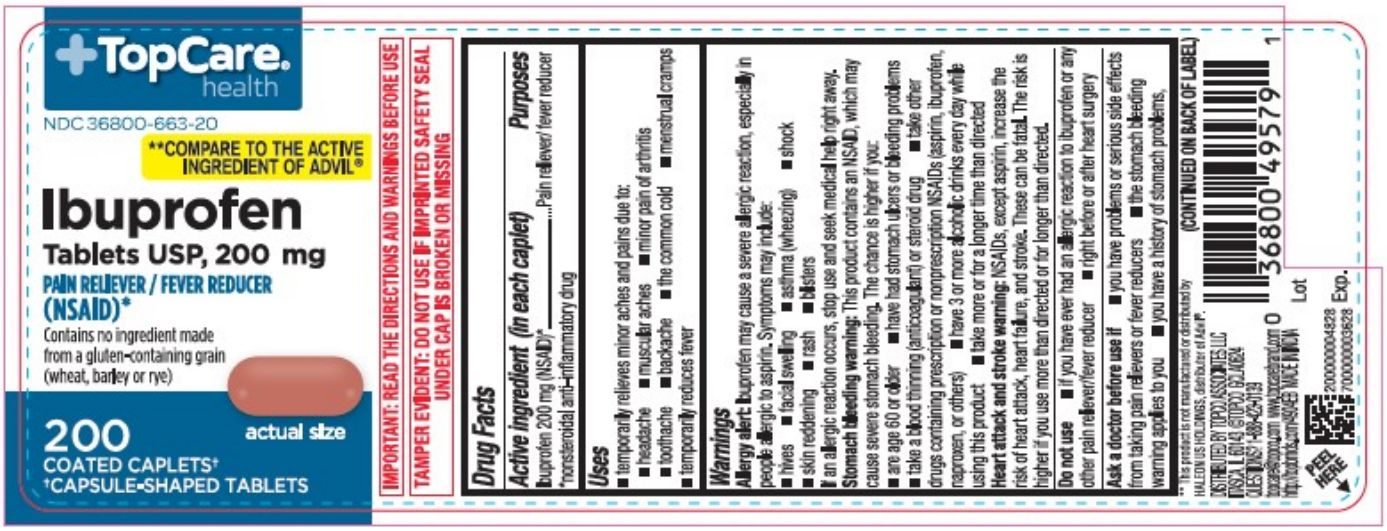
Inactive ingredients

colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

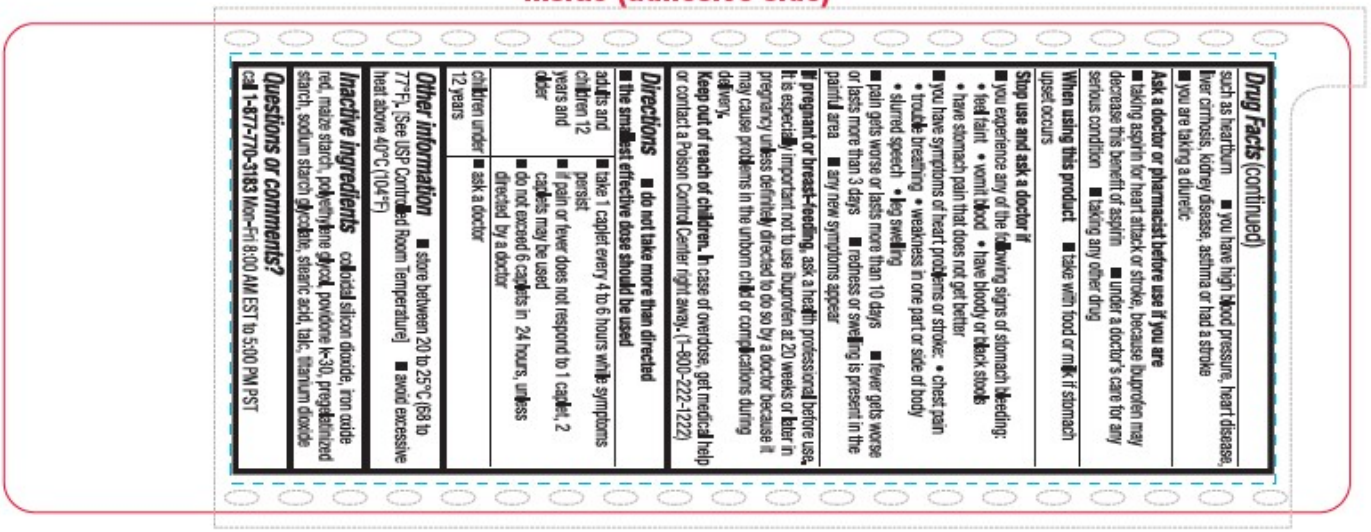
Questions or comments?

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:36800-663
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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	red ((Reddish Brown))	**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:36800-663-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	10/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	10/17/2024	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 11/2024 TOPCO ASSOCIATES LLC