

IBUPROFEN- ibuprofen tablet, film coated
Preferred Pharmaceuticals Inc.

Major Pharmaceuticals Ibuprofen Tablets, 200mg Drug Facts

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

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 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

- 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)

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

Questions or comments?

1-800-616-2471

Repackaged By: Preferred Pharmaceuticals Inc.

Principal Display Panel

SEE NEW WARNINGS

Ibuprofen Tablets, 200mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

COMPARE TO the active ingredient of ADVIL®

** Capsule Shaped Tablets

Repackaged By: Preferred Pharmaceuticals Inc.

<p>Ibuprofen Tab. 200mg</p> <p>Generic for Motrin</p> <p>Each tablet contains: Ibuprofen USP, 200mg (NSAID) ...Pain reliever/fever reducer</p> <p>Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Major Pharm.; Livonia, MI Prod#:</p> <p>Warning Ibuprofen may cause a severe allergic reaction especially in people allergic to aspirin. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer, or right before or after heart surgery. This product contains an NSAID, which may cause severe stomach bleeding. If pregnant or breast-feeding, ask a health professional before use. Store at 20°-25°C (68°-77°F) avoid high humidity and excessive heat 40°C (104°F). Keep out of reach of children. Tablet is oval, brown, imprinted with I-2.</p>	 <p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p>	<p>Ibuprofen Tab. 200mg Qty: Ins: Lot#: Bat#:</p> <p>Prod# (NDC):</p> <p>Ibuprofen Tab. 200mg Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Ibuprofen Tab. 200mg Qty: Insurance NDC: Lot#: Bat#:</p> <p>Ibuprofen Tab. 200mg Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p>Log</p> <p>Chart</p> <p>Billing</p> <p>Patient</p>
<p>Directions English</p> <p>Take ___ capsule(s) every ___ hour(s). Use as directed by your doctor</p>		<p>Instrucciones Español:</p> <p>Toma ___ capsula(s) cada ___ horas. Uso según lo dirigido por su doctor</p>	

IBUPROFEN			
ibuprofen tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8148(NDC:0904-7912)
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
STARCH, CORN (UNII: O8232NY3SJ)			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BROWN	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	I2
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8148-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
2	NDC:68788-8148-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
3	NDC:68788-8148-4	40 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
4	NDC:68788-8148-5	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
5	NDC:68788-8148-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
6	NDC:68788-8148-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	
7	NDC:68788-8148-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072096	03/03/2022	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment			
Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-8148)