

**IBUPROFEN- ibuprofen tablet, film coated**  
**Preferred Pharmaceuticals Inc.**

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**Major Pharmaceuticals Ibuprofen Drug Facts**

**Active ingredient (in each tablet)**

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:**

**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?**

**1-800-719-9260**

**Principal Display Panel**

SEE NEW WARNINGS

Ibuprofen Tablets, 200mg

PAIN RELIEVER / FEVER REDUCER (NSAID)

COMPARE TO the active ingredient of ADVIL®

# Ibuprofen Tablets 200mg

Generic for Motrin

Each tablet contains: Ibuprofen 200mg .. pain  
reliever/ fever reducer

Pkg Size: Exp Date:

Lot#:

Batch#:

Ins:

Mfg: Major Pharm.; Livonia, MI

Prod#:

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. 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. 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 round,  
brown, imprinted with 12.



CAUTION: Federal law PROHIBITS transfer of  
this drug to any person other than the patient for  
whom it was prescribed

Ibuprofen Tablets 200mg

Qty: Ins:  
Lot#: Bat#:

Prod# (NDC):

Ibuprofen Tablets 200mg

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

Ibuprofen Tablets 200mg

Qty: Ins:

Insurance NDC:

Lot#: Bat#:

Ibuprofen Tablets 200mg

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):



Directions English

Take \_\_\_ tablet(s)  
every \_\_\_ hours.  
Use as directed by your  
doctor



Instrucciones Espanol:

Toma \_\_\_ tableta(s)  
cada \_\_\_ horas.  
Uso según lo dirigido  
por su doctor

Log

Chart

Billing

Patient

## IBUPROFEN

ibuprofen tablet, film coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7983(NDC:0904-6747)
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE 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	ROUND	Size	10mm
Flavor		Imprint Code	12
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7983-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2021	
2	NDC:68788-7983-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2021	
3	NDC:68788-7983-5	50 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2021	
4	NDC:68788-7983-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/05/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA072096	08/05/2021	

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

## Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	REPACK(68788-7983)

Revised: 7/2023

Preferred Pharmaceuticals Inc.