

**IBUPROFEN- ibuprofen tablet, coated**  
**Marc Glassman, Inc.**

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**1111C-MAR-2025-0714**

***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 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 tablet every 4 to 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: ask a doctor

## **Other information**

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

## **Inactive ingredients**

colloidal silicon dioxide, corn starch, FD&C yellow #6, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

## **Questions or comments?**

1-844-705-4384

## **PRINCIPAL DISPLAY PANEL**

Marc's®

NDC 68998-011-03

†Compare to the active ingredient in Motrin® IB

Ibuprofen

Tablets, 200 mg

PAIN RELIEVER / FEVER REDUCER

Actual Size

100 COATED TABLETS

**DO NOT USE IF IMPRINTED SEAL  
UNDER CAP IS BROKEN OR MISSING**



**Active ingredient (in each tablet) Purposes**  
Ibuprofen 200 mg (NSAID)\* .....Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

- 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

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed
- have heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. The risk is higher if
  - you are age 60 or older
  - you have had stomach ulcers or bleeding problems
  - you have blood thinning (anticoagulant) or steroid drug
  - you take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

**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

- you have preexisting or serious side effects from taking pain relievers or other 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

- 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

■ Take with food or milk if stomach upset occurs

- you experience any of the following signs at 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
- big 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

during delivery.  
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center away; (1-800-222-1222)

**Directions** ■ do not take more than directed

<ul style="list-style-type: none"> <li>■ the smallest effective dose should be used</li> </ul>	<ul style="list-style-type: none"> <li>■ take 1 tablet every 4 to 6 hours while symptoms persist</li> <li>■ if pain or fever does not respond to 1 tablet, 2 tablets may be used</li> <li>■ do not exceed 6 tablets in 24 hours, unless directed by a doctor</li> <li>■ ask a doctor</li> </ul>
<ul style="list-style-type: none"> <li>■ children under 12 years</li> </ul>	

- read all warnings and cautions before use
- store between 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

dicarboxide, xanthan starch, FD&C yellow #6, polyethylene glycol, polyvinyl alcohol, povidone K30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Questions or comments?** 1-844-705-4339

**ibuprofen**  
Tablets, 200 mg  
PAIN RELIEVER / FEVER REDUCER (NSAID)

**Important: Read all product information before using. Keep this box for important information.**

Distributed by:  
Marc Glassman, Inc.  
West 130th Street  
Cleveland, OH 44130  
Made in India

**Ibuprofen**  
Tablets, 200 mg

Tablets, 200 mg

### PAIN RELIEVER / FEVER REDUCER (NSAID)

100 COATED TABLETS



ON

COATING FREE AREA

ON

CZ

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-011
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G2
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-011-03	1 in 1 CARTON	05/01/2020	
1		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202312	05/01/2020	

**Labeler** - Marc Glassman, Inc. (094487477)