

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

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**1111 - MAR - 2018-1206**

***Drug Facts***

**Active ingredient (in each tablet)**

Ibuprofen, USP 200 mg (NSAID <sup>1</sup>)

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<sup>1</sup> nonsteroidal anti-inflammatory drug

**Purpose**

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 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

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, or asthma
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

**Stop use and ask a doctor if**

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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
- 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.

**Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)

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- take 1 tablet every 4 to 6 hours while symptoms persist

adults and children 12 years and over	<ul style="list-style-type: none"><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></ul>
children under 12 years	<ul style="list-style-type: none"><li>• ask a doctor</li></ul>

### **Other information**

- store between 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)
- read all warnings and directions before use
- retain carton for complete product information

### **Inactive ingredients**

colloidal silicon dioxide, corn starch, hypromellose, FD&C yellow #6 aluminum lake, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone K30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide, triacetin

### **PRINCIPAL DISPLAY PANEL**

† Compare to the active ingredient in Motrin® IB

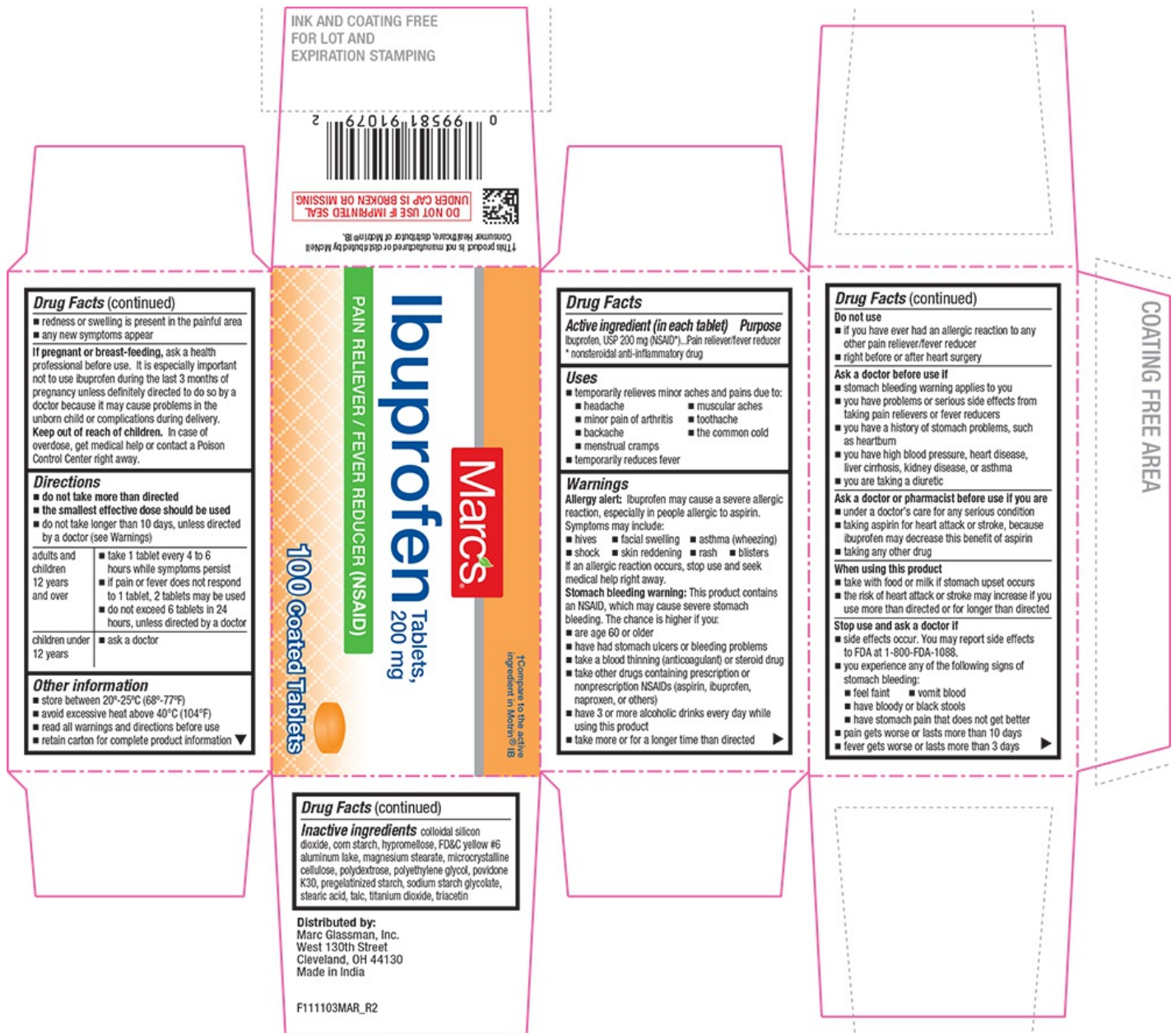
Marc's®

Ibuprofen

Tablets, 200 mg

Pain Reliever/Fever Reducer (NSAID)

100 Coated Tablets



## IBUPROFEN

ibuprofen tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68998-111
<b>Route of Administration</b>	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
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SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STARCH, CORN (UNII: O8232NY3SJ)
HYPROMELLOSES (UNII: 3NXW29V3WO)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
ALUMINUM OXIDE (UNII: LM26O6933)
MAGNESIUM STEARATE (UNII: 70097M6I30)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
POLYDEXTROSE (UNII: VH2XOU12IE)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE K30 (UNII: U725QWY32X)
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)
STEARIC ACID (UNII: 4ELV7Z65AP)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIACETIN (UNII: XHX3C3X673)

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	IBU;200
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-111-03	1 in 1 CARTON	06/01/2009	
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	ANDA091355	06/01/2009	

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