

**MOTRIN IB- ibuprofen tablet, film coated**  
**R J General Corporation**

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**MOTRIN<sup>®</sup> IB**

***Drug Facts***

**Active ingredient (in each caplet)**

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

<sup>1</sup> 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	<ul style="list-style-type: none"> <li>▪ take 1 caplet every 4 to 6 hours while symptoms persist</li> <li>▪ if pain or fever does not respond to 1 caplet, 2 caplets may be used</li> <li>▪ do not exceed 6 caplets 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

- 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)
- **do not use if pouch is torn or damaged**

### Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

### Questions?

Call **1-877-895-3665** (toll-free) or **215-273-8755** (collect) or visit [www.motrin.com](http://www.motrin.com)

**Distributed by:**

JOHNSON & JOHNSON CONSUMER INC.  
McNeil Consumer Healthcare Division  
Fort Washington, PA 19034 USA

**Repackaged and distributed by:**

RJ General  
2024 Northwest Drive  
Cincinnati OH 45231

**PRINCIPAL DISPLAY PANEL - 200 mg Tablet Pouch Box**

**Motrin<sup>®</sup> IB**

**Ibuprofen Tablets USP, 200 mg**

**Pain Reliever / Fever Reducer (NSAID)**

Convenient

Take-Along

Packs

**Coated Caplets\*\***

**\*\*Capsule-Shaped Tablets**

Convenient

Take-Along

Packs

**50 Pouches of 2 Coated Caplets\*\* Each**

**Total 100 Coated Caplets\*\***

\*\*Capsule-Shaped Tablets

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Total 100 Coated Caplets\*\***

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- you are taking a diuretic

### Drug Facts (continued)

■ 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
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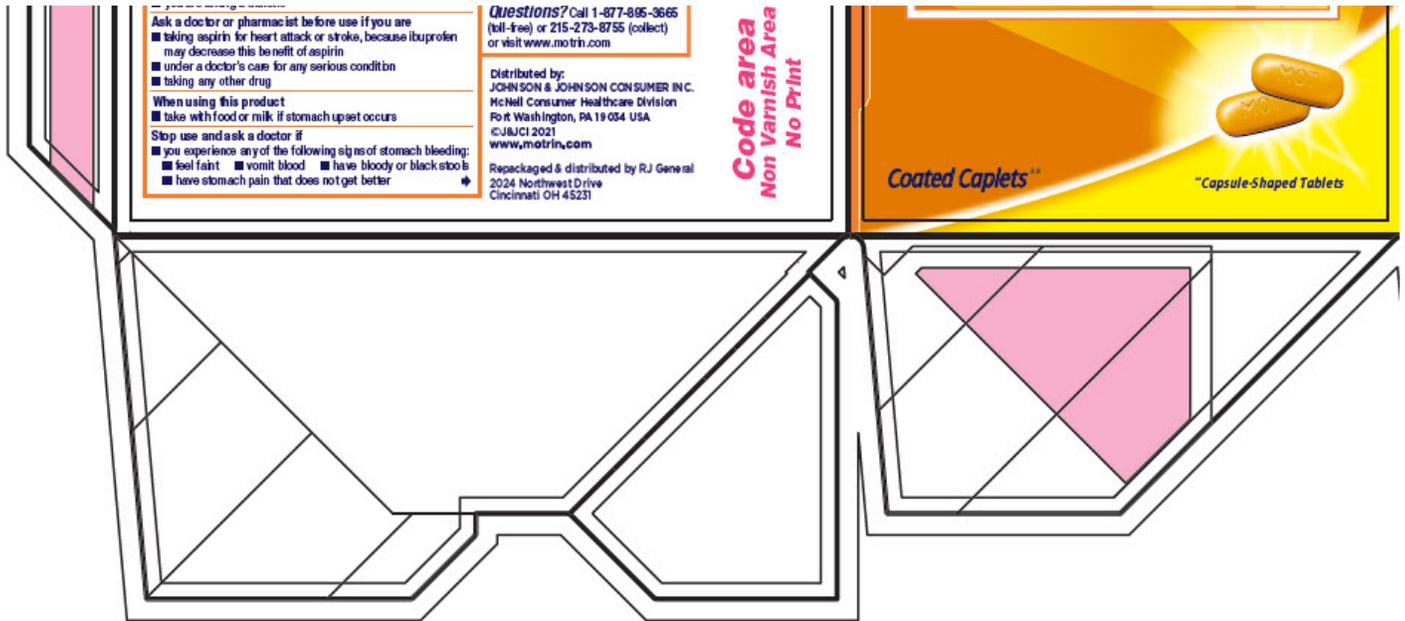
colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide



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Ibuprofen Tablets USP, 200 mg  
Pain Reliever / Fever Reducer (NSAID)

Convenient  
Take-Along  
Packs



## MOTRIN IB

ibuprofen tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70264-029(NDC:50580-230)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	MOT
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70264-029-01	50 in 1 BOX	05/01/2021	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	05/01/2021	

**Labeler** - R J General Corporation (122542830)

### Establishment

Name	Address	ID/FEI	Business Operations
R J General Corporation		122542830	repack(70264-029)

### Establishment

Name	Address	ID/FEI	Business Operations
Johnson & Johnson		878046358	manufacture(70264-029)

Revised: 10/2023

R J General Corporation