

MOTRIN IB- ibuprofen tablet, film coated
Johnson & Johnson Consumer Inc.

Motrin IB

Drug Facts

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID) ¹

¹ 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	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ ask a doctor

Other information

- read all warnings and directions before use
- store between 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, 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

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

PRINCIPAL DISPLAY PANEL

See Revised Warning

NDC 50580-230-03

Motrin[®] IB

Ibuprofen Tablets USP, 200 mg

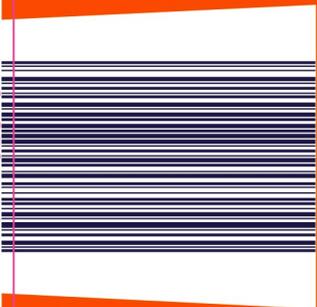
Pain Reliever / Fever Reducer (NSAID)

Actual Size

100 Coated Caplets**

**Capsule-Shaped Tablets

8K078MN C4



See Revised Warning

NDC 50580-230-03

Motrin[®] IB

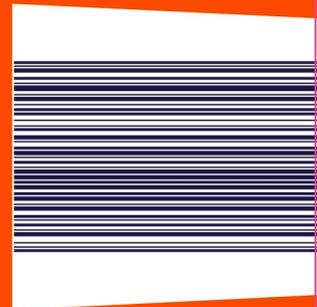
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Pain Reliever / Fever Reducer (NSAID)

100 Coated Caplets**



**Capsule-Shaped Tablets



8K078MN C4

Motrin[®] IB
Pain Reliever / Fever Reducer (NSAID)
Ibuprofen Tablets USP, 200 mg

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

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JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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Drug Facts (continued)

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Do not use if foil inner seal is imprinted
SEALED for YOUR PROTECTION is broken or missing.



3 0045-0481-01 6

CODE
AREA

8K078 MN C4

Drug Facts (continued)

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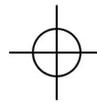
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MOTRIN IB

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-230
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
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Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	MOT
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-230-01	1 in 1 CARTON	07/01/2016	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50580-230-02	1 in 1 CARTON	07/01/2016	
2		60 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:50580-230-03	1 in 1 CARTON	07/01/2016	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:50580-230-04	1 in 1 CARTON	07/01/2016	
4		225 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:50580-230-05	1 in 1 CARTON	07/01/2016	
5		300 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:50580-230-06	1 in 1 CARTON	07/01/2016	
6		500 in 1 BOTTLE; Type 0: Not a Combination		

		Product		
7	NDC:50580-230-07	1 in 1 CARTON	07/17/2017	
7		24 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:50580-230-08	2 in 1 POUCH; Type 0: Not a Combination Product	06/30/2017	
9	NDC:50580-230-09	50 in 1 CARTON	04/24/2017	
9		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
ANDA	ANDA077349	07/01/2016	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023

Johnson & Johnson Consumer Inc.