

MOTRIN IB- ibuprofen tablet, film coated
Jones Contract Packaging Services

Motrin IB

Drug Facts

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)*

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 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"> • 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 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, 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

Package Labeling:

See New Warnings

Motrin^{IB}
Ibuprofen Tablets USP, 200 mg
Pain Reliever / Fever Reducer (NSAID)

Convenient Take-Along Packs

Coated Caplets**

Drug Facts

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

Uses

- temporarily relieves minor aches and pains due to:
 - muscular aches
 - headache
 - minor pain of arthritis
 - backache
 - menstrual cramps
 - temporary 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 worsening, skin redness, 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 65 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

Heart attack and stroke warning (NSAIDs): Except aspirin, excess use of 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

Other information

- read all warnings and directions before use
- store at 20°-25° (68°-77°)
- 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 oxide, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

Questions? Call 1-877-895-5865 (toll-free) or 215-273-8756 (collect) or visit www.motrin.com

Distributed by: JOHNSON & JOHNSON CONSUMER INC. Medical Consumer Healthcare Division, Fort Washington, PA 19054 USA

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See New Warnings

Motrin^{IB}
Ibuprofen Tablets USP, 200 mg
Pain Reliever / Fever Reducer (NSAID)

Convenient Take-Along Packs

Coated Caplets**

Actual Size of Pouch

50 Pouches of 2 Coated Caplets** Each
Total 100 Coated Caplets**

Coated Caplets**

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MOTRIN IB

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67414-240
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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	16 mm
Flavor		Imprint Code	MOT
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67414-240-09	50 in 1 CARTON	01/25/2018	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67414-240-00	2500 in 1 BOX	01/25/2018	
2		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 - Jones Contract Packaging Services (243697187)

Registrant - Jones Contract Packaging Services (243697187)

Establishment

Name	Address	ID/FEI	Business Operations
L. Perrigo Company		006013346	manufacture(67414-240)

Establishment

Name	Address	ID/FEI	Business Operations
Jones Contract Packaging Services		243697187	pack(67414-240)

Revised: 8/2018

Jones Contract Packaging Services