

MOTRIN IB MIGRAINE- ibuprofen capsule, liquid filled
Johnson & Johnson Consumer Inc.

Motrin IB Migraine

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID) ¹ (present as the free acid and potassium salt)

¹ nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Use

- treats migraine

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

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.

Medication overuse headache warning

Headaches may worsen if this product is used for 10 or more days per month.

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

- you have never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you have experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- 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, asthma, or had a stroke
- 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

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
- migraine headache pain is not relieved or gets worse after the first dose
- 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	<ul style="list-style-type: none"> ▪ take 2 capsules with a glass of water ▪ if symptoms persist or worsen, ask your doctor ▪ do not take more than 2 capsules in 24 hours, unless directed by a doctor
under 18 years of age	<ul style="list-style-type: none"> ▪ ask a doctor

Other information

- each capsule contains: **potassium 20 mg**
- read all directions and warnings before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.
- **do not use if foil inner seal imprinted with "Sealed For Your Safety" is broken or missing**

Inactive ingredients

gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

PRINCIPAL DISPLAY PANEL

See Revised Warning

NDC 50580-120-80

Motrin[®] IB

MIGRAINE

Ibuprofen Capsules, 200 mg

Pain Reliever (NSAID)

80 Liquid Filled Capsules

Actual Size



MOTRIN IB MIGRAINE

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50580-120
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
 McNeil Consumer Healthcare Division
 Fort Washington, PA 19034 USA ©J&JCI 2022
www.motrin.com Pat. www.jjciipats.com



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

Drug Facts

Active ingredient (in each capsule) Purpose
 Soluble ibuprofen equal to 200 mg ibuprofen (NSAID).....Pain reliever
 *nonsteroidal anti-inflammatory drug

Use
 ■ treats migraine

Warnings
 Allergic alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
 ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin redness ■ rash ■ blisters
 If an allergic reaction occurs, stop use and seek medical help right away.
 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 other drugs containing aspirin 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, 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.
Medication overdose headache warning: Headaches may worsen if this product is used for 10 or more days per month.

Do not use
 ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer
 ■ right before or after heart surgery
 ■ if you have a headache that is different from your usual migraines
 ■ you have the worst headache of your life
 ■ you have fever and stiff neck
 ■ you have had a seizure or convulsions
 ■ you have a history of stomach problems, such as heartburn, kidney disease, asthma, or had a stroke
 ■ 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
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

Drug Facts (continued)

Do not use
 ■ if you have ever had an allergic reaction to any other pain reliever/fever reducer
 ■ right before or after heart surgery
 ■ if you have a headache that is different from your usual migraines
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Drug Facts (continued)
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 gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol
 Questions or comments?
 call 1-877-895-3665 (toll-free) or 215-271-8755 (collect)

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
 ■ migraine headache pain is not relieved or gets worse after the first dose
 ■ 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 definitively 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
 ■ the smallest effective dose should be used
 ■ do not take more than directed

adults	take 2 capsules with a glass of water if symptoms persist or worsen, ask your doctor
under 18 years of age	ask a doctor

Other information
 ■ each capsule contains potassium 20 mg
 ■ store at 20-25 °C (68-77 °F)
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 ■ do not use if inner seal imprinted with "Sealed For Your Safety" is broken or missing

See Revised Warning



30052507



Inactive Ingredients

Ingredient Name	Strength
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	white (Clear)	Score	no score
Shape	OVAL (Oblong)	Size	20mm
Flavor		Imprint Code	Motrin;IB
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50580-120-20	1 in 1 CARTON	01/18/2021	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50580-120-80	1 in 1 CARTON	01/18/2021	
2		80 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	ANDA078682	01/18/2021	

Labeler - Johnson & Johnson Consumer Inc. (878046358)

Revised: 3/2023

Johnson & Johnson Consumer Inc.