IBUPROFEN- ibuprofen tablet, coated
Shield Pharmaceuticals Corp

Ibuprofen

Drug Facts

Active ingredient (in each liquid-filled capsule)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache _ toothache
- backache
- menstrual cramps
- the common cold
- muscular aches
- minor pain of arthritis
- 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 a nonsteroidal anti-inflammatory drug (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.

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
- the stomach bleeding warning applies to you
- you have problems or serious side effects from takin
- 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
- 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 (1-800-222-1222) right away.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: 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: ask a doctor

Other information

- store between 20˚-25˚C (68˚-77˚F)

Inactive ingredients

colloidal silicon dioxide, FD&C yellow #6, maize starch, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, talc titanium dioxide

Questions or comments?

1-800-373-6981

Distributed by:
Shield Pharmaceuticals Corp.
Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL

Ibuprofen 200 mg

Carton

Drug Facts (continued)
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ValuRx
Compare to Motrin® IB Caplets active ingredient†
$7.25
ibuprofen
Ibuprofen Tablets, 200 mg
Pain Reliever/ Fever Reducer (NSAID)
Actual Size
40 caplets
TAMPER EVIDENT : DO NOT USE IF CARTON IS OPENED OR SAFETY SEAL UNDER CAP IS BROKEN OR MISSING
406118
6 11419 40611 8
LOT:
EXP:
KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.
Drug Facts (continued)
Questions or comments?
1-800-373-6841
This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Motrin® IB Caplets
Distributed by:
Shield Pharmaceuticals Corp.
Ronkonkoma, NY 11779
Made in India REV. 03/25
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Active ingredient (in each caplet) Purpose
Ibuprofen ..... Pain reliever/
200 mg (NSAID)* ..... fever reducer
*nonsteroidal anti-inflammatory drug
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■ right before or after heart surgery
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■ you have a history of stomach problems, such as heartburn
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■ have bloody or black stools
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■ chest pain ■ trouble breathing
■ leg swelling ■ slurred speech

Label

Drug Facts (continued)

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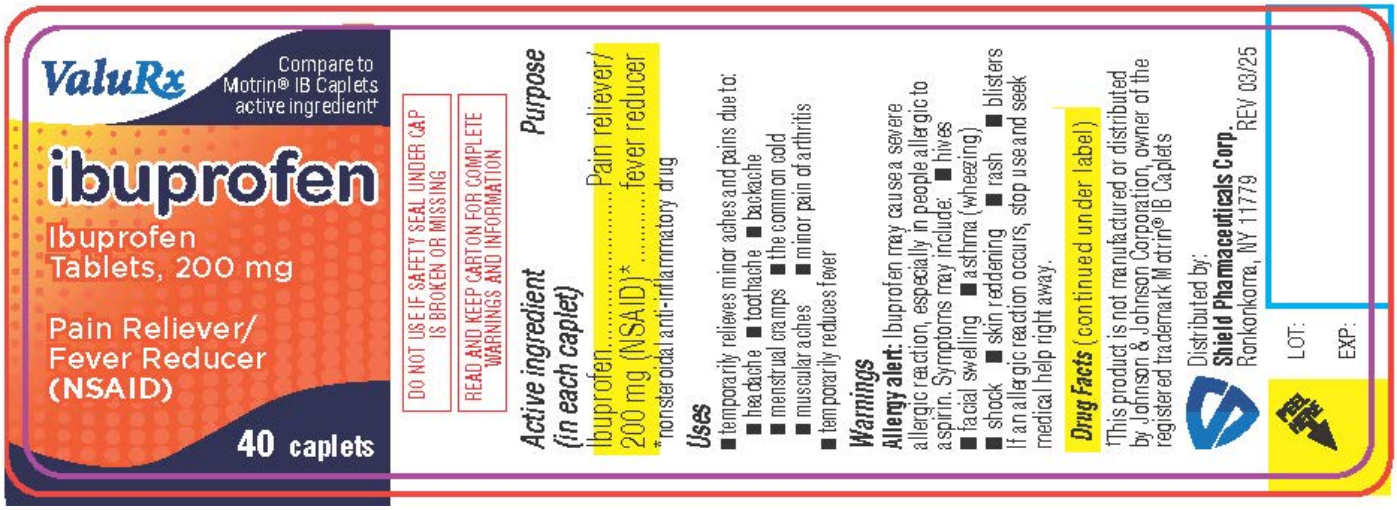

IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:83059-0082
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, POTATO (UNII: 8I089SAH3T)	

POVIDONE (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	11mm
Flavor		**Imprint Code**	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0082-4	1 in 1 CARTON	03/16/2025	
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202312	03/16/2025	

Labeler - Shield Pharmaceuticals Corp (118724924)

Revised: 3/2025 Shield Pharmaceuticals Corp