

**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 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
- 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, croscarmellose sodium, D&C yellow #10, FD&C blue #2, FD&C yellow #6, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, 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



THIS PRODUCT IS NOT TO BE USED IN CHILDREN UNDER 12 YEARS OF AGE. FOR MORE INFORMATION, CONTACT YOUR PHARMACEUTICAL SUPPLIER.

**Drug Facts (continued)**

- weakness in one part or side of body
- 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 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, Croscarmellose sodium, D&C YELLOW #10, FD&C Blue #2, FD&C Yellow #8, Lecithin, Magnesium Stearate, Microcrystalline cellulose, Polyethylene glycol, Polyvinyl Alcohol, Pregelatinized starch, Talc, Titanium Dioxide

**ValuRx** Compare to Motrin® IB Caplets active ingredient\* **\$1.25**

# ibuprofen

## Ibuprofen Tablets, 200 mg

### Pain Reliever/ Fever Reducer (NSAID)



Actual Size

## 40 caplets

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

**Drug Facts (continued)**  
**Questions or comments?**  
1-800-373-6981

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Motrin® IB Caplets

Distributed by:  
**Shield Pharmaceuticals Corp.**  
Hauppauge, NY 11788  
Made in China ORG 01/24

**Drug Facts**

Active ingredient (in each caplet)	Purpose
Ibuprofen	Pain reliever/ fever reducer
*nonsteroidal anti-inflammatory drug	

- 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 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

**Drug Facts (continued)**

**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 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 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
  - leg swelling ■ slurred speech

Label

**Drug Facts (continued)**  
**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 and nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ use 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.  
**Ask a doctor before use if**  
 ■ the 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 disease, kidney disease, asthma or had a stroke ■ you are taking a diuretic  
**Directions**  
 ■ do not take more than directed ■ the smallest effective dose should be used ■ adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 capsule, 2 capsules may be used ■ do not exceed 6 capsules 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)  
**Questions or comments?**  
 1-800-373-6981

**ValuRx** Compare to Motrin® IB Caplets active ingredient

**ibuprofen**  
 Ibuprofen Tablets, 200 mg  
 Pain Reliever/  
 Fever Reducer (NSAID)  
 40 caplets

**DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**  
**READ AND KEEP CAUTION FOR COMPLETE WARNINGS AND INFORMATION**

**Active ingredient (in each caplet)**  
 ibuprofen  
 200 mg (NSAID) - fever reducer/ 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.

**Drug Facts (continued under label)**  
 Distributed by:  
**Shield Pharmaceuticals Corp.**  
 Hauppauge, NY 11788 ORG 01/24

03.965A LOT: EXP:

# IBUPROFEN

ibuprofen tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83059-0020
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35S5W5USQ3G)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

<b>Product Characteristics</b>			
<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	13103
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0020-4	1 in 1 CARTON	01/26/2024	
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207095	01/26/2024	

**Labeler** - Shield Pharmaceuticals Corp (118724924)