

**ASSURED IBUPROFEN- ibuprofen tablet, film coated**  
**Spirit Pharmaceuticals LLC**

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**Ibuprofen Tablets USP 200 mg**

**Drug Facts**

**Drug Facts**

**Active ingredient  
(in each caplet)**

Ibuprofen 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pain 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

### **Drug Facts** (continued)

**Heart attack and stroke warning** NSAID's except aspirin increases 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

## **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:

## **Drug Facts** (continued)

- chest pain → trouble breathing
- leg swelling → slurred speech
- 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**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- 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**

- read all warnings and directions before use.
- store between 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

## **Drug Facts** (continued)

## Inactive ingredients

colloidal silicon dioxide, FD&C yellow no. 6, maize starch, polyethylene glycol, polyvinyl alcohol, povidone k30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide.

## Questions or comments?

1-888-333-9792

## PRINCIPAL DISPLAY PANEL

Ibuprofen

Ibuprofen Tablets 200 mg -

Pain reliever/fever reducer (NSAID)

**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) ■ have 3 or more alcoholic drinks every day while using this product

**Heart attack and stroke warning:** NSAIDs except aspirin increases 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 cirrhosis, kidney disease, asthma or had a stroke
- you are taking a diuretic

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**Questions or comments? 1-888-333-9792**

**VALUHEALTH**  
BY SPIRIT

**ibuprofen**  
Ibuprofen Tablets, USP  
200 mg -  
Pain Reliever /  
Fever Reducer (NSAID)

40 caplets

DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

**Purpose**

Ibuprofen 200 mg (NSAID)\*, ..... Pain reliever/fever reducer  
\*nonsteroidal anti-inflammatory drug

**Uses**

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  - muscular aches ■ minor pain of arthritis
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**Warnings**

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ stock ■ skin reddening ■ rash ■ blisters

If an allergic reaction occurs, stop use and seek medical help right away.

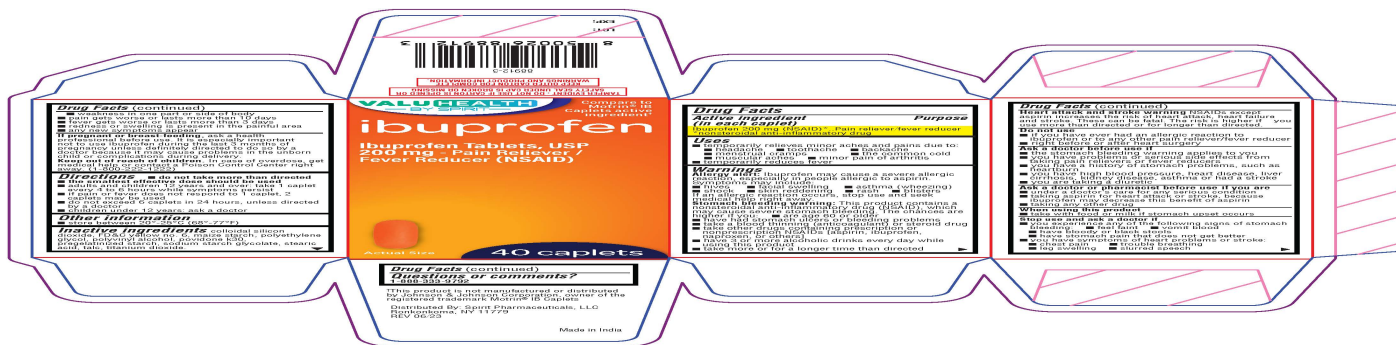
**Drug Facts (continued under label)**

Distributed By: Spirit Pharmaceuticals, LLC  
Ronkonkoma, NY 11779  
REV 02/23

88912-3

Made in India

LOT:  
EXP:



## ASSURED IBUPROFEN

ibuprofen tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-4139
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	G2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:68210			

<b>1</b>	NDC: 68210-4139-4	1 in 1 CARTON	04/28/2021	
<b>1</b>		40 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA202312		02/25/2019	

**Labeler** - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023

Spirit Pharmaceuticals LLC