

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

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**Assured™ Ibuprofen Tablets**

***Drug Facts***

**Active ingredient (in each tablet)**

Ibuprofen 200 mg (NSAID)\*

**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**

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 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 stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- 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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- 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 tablet every 4 to 6 hours while symptoms persist

- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

### Other information

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

### Inactive ingredients

Colloidal silicon dioxide, croscarmellose sodium\*, iron oxide red, magnesium stearate\*, microcrystalline cellulose\*, polyethylene glycol, polyvinyl alcohol, povidone k-30\*, pregelatinized starch, sodium starch glycolate\*, stearic acid\*, talc, titanium dioxide.

\*contains one or more of these ingredients

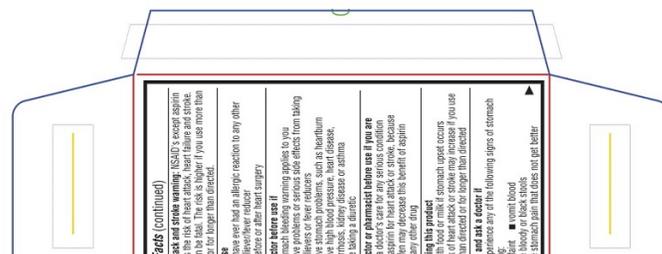
### Questions or comments?

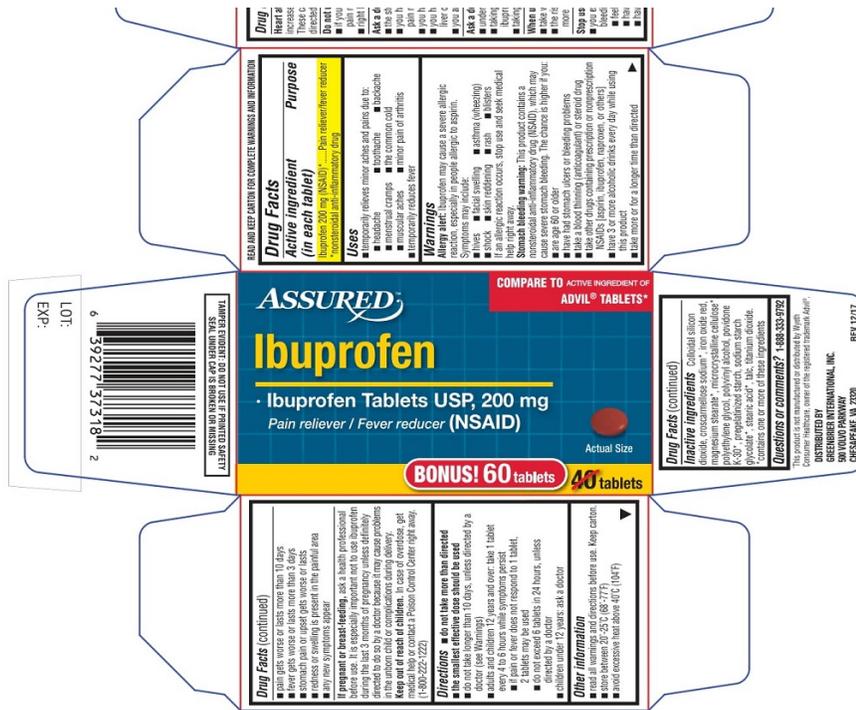
1-888-333-9792

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500 VOLVO PARKWAY, CHESAPEAKE, VA 23320**

### PRINCIPAL DISPLAY PANEL-BOTTLE CARTON

ASSURED™  
COMPARE TO ACTIVE INGREDIENT OF  
ADVIL® TABLETS\*  
Ibuprofen  
• Ibuprofen Tablets USP, 200 mg  
Pain reliever / Fever reducer (NSAID)  
Actual Size  
BONUS! 60 tablets  
40 tablets





# ASSURED IBUPROFEN

ibuprofen tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68210-0081
<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)				
STARCH, CORN (UNII: O8232NY3SJ)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE K30 (UNII: U725QWY32X)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	brown	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	G2	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0081-6	1 in 1 CARTON	12/22/2017	
1		60 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68210-0081-3	1 in 1 CARTON	10/24/2018	
2		30 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	ANDA079174	12/15/2017		

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

### Establishment

Name	Address	ID/FEI	Business Operations
Granules India Ltd.		918609236	manufacture(68210-0081)