

**IBUPROFEN- ibuprofen capsule, liquid filled**  
**SPIRIT PHARMACEUTICALS,LLC**

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**IBUPROFEN SOFTGEL**

***Drug Facts***

***Active ingredients (in each Capsule)***

Solubilized ibuprofen equal to 200 mg ibuprofen (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 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 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**

- **each capsule contains:** potassium 20 mg
- 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**

FD&C blue 1, gelatin, gelatin (hydrolyzed), isopropyl alcohol, medium chain triglyceride, PEG 600, potassium hydroxide, propylene glycol, shellac resins, sodium lauryl sulphate, sorbitol and sorbitan solution, titanium dioxide, white edible oil

### **PRINCIPAL DISPLAY PANEL**

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**Drug Facts (continued)**

**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

**Directions** ■ do not take more than directed

■ the smallest effective dose should be used

■ adults and children 12 years and over: take 1 softgel every 4 to 6 hours while symptoms persist

■ if pain or fever does not respond to 1 softgel,

2 softgels may be used  
■ do not exceed 6 softgels in 24 hours, unless directed by a doctor

■ children under 12 years: ask a doctor

**Other information**

■ each softgel contains: potassium 20 mg

■ 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)

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

VALUHEALTH

ibuprofen

Solubilized Ibuprofen  
Softgels 200 mg -  
Pain Reliever /  
Fever Reducer (NSAID)

6 softgels

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

KEEP OUTER CARTON FOR COMPLETE  
WARNINGS AND PRODUCT INFORMATION.

**Active ingredient  
(in each softgel)**

Solubilized ibuprofen equal to Pain reliever/  
200 mg ibuprofen (NSAID)\* .....Fever reducer  
(present as the free acid and potassium salt)  
\* nonsteroidal anti-inflammatory drug

**Purpose**

**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: Spirit Pharmaceuticals, LLC  
Ronkonkoma, NY 11779  
ORIG 01/21

88913-0

Made in India

LOT:

EXP:

PEEL  
HERE



<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>SORBITAN</b> (UNII: 6O92ICV9RU)
<b>GELATIN</b> (UNII: 2G86QN327L)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>GELATIN HYDROLYZATE (PORCINE SKIN, MW 3000)</b> (UNII: 0K9R94573C)
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)
<b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SHELLAC</b> (UNII: 46N107B71O)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong shaped)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	469
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4205-6	1 in 1 PACKAGE	07/21/2022	
1		6 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	ANDA204469	07/21/2022	

**Labeler** - SPIRIT PHARMACEUTICALS,LLC (179621011)

Revised: 12/2023

SPIRIT PHARMACEUTICALS,LLC