

IBUPROFEN- ibuprofen capsule, liquid filled
SPIRIT PHARMACEUTICALS,LLC

VALUMEDS™ IBUPROFEN SOFTGELS

Drug Facts

Active ingredient (in each Capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)*
(present as the free acid and potassium salt)

*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

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 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)

Inactive ingredients

Ammonium hydroxide, FD&C green no. 3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, propylene glycol, potassium hydroxide, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

Distributed By:

SPIRIT PHARMACEUTICALS LLC.

RONKONKOMA, NY 11779

PRINCIPAL DISPLAY PANEL - 200 mg Capsule Bottle Carton

SEE NEW WARNINGS INFORMATION

VALUMEDS™

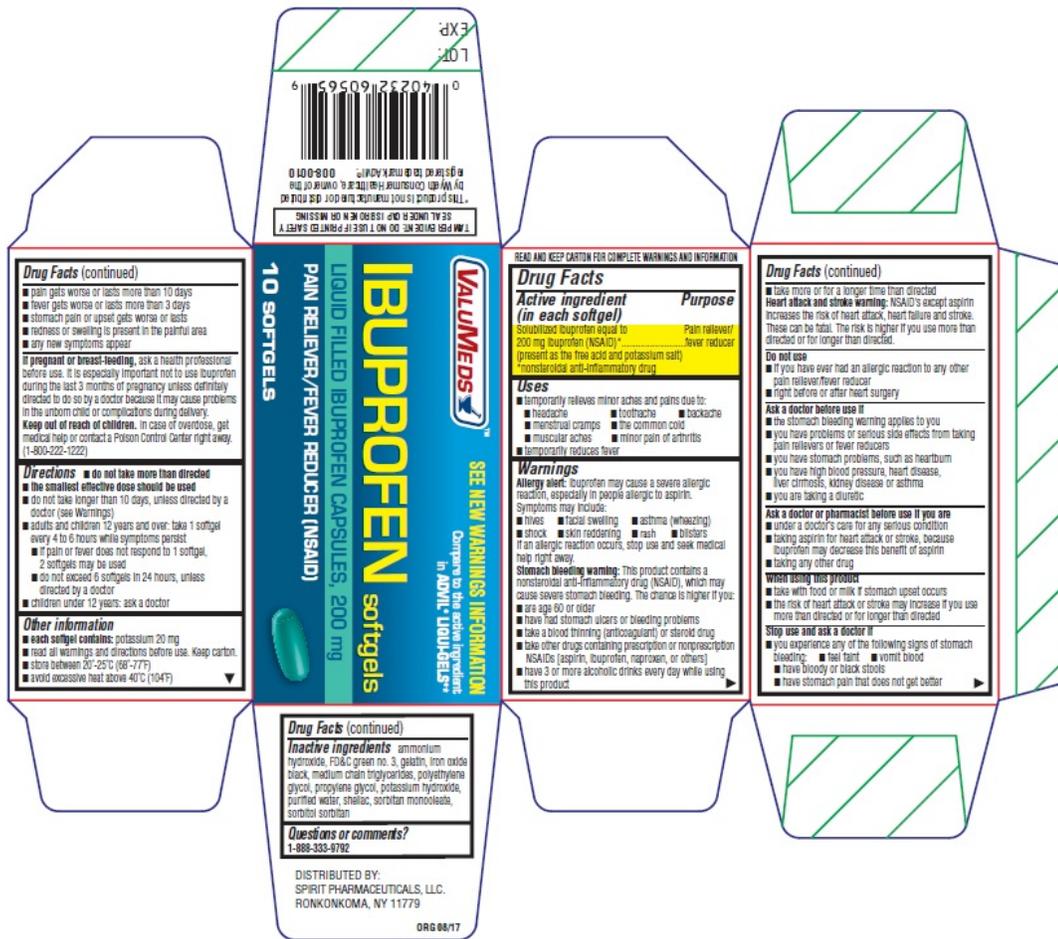
**Compare to the active ingredient
in Advil® Liqui-Gels®***

IBUPROFEN softgels

LIQUID FILLED IBUPROFEN CAPSULES, 200 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

10 SOFTGELS



IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0200
Route of Administration	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
AMMONIA (UNII: 5138Q19F1X)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GELATIN (UNII: 2G86QN327L)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	133
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0200-1	1 in 1 CARTON	04/10/2018	
1		10 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	ANDA079205	04/10/2018	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Registrant - SPIRIT PHARMACEUTICALS,LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
Marksans Pharma Ltd		925822975	manufacture(68210-0200)