

**VALUMEDS IBUPROFEN- ibuprofen tablet, film coated**  
**SPIRIT PHARMACEUTICALS LLC**

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**VALUMEDS 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

#### **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**
- 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
- 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, pregelatinized starch, talc, titanium dioxide.

**Questions or comments?**

**1-888-333-9792**

Distributed By

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

**PRINCIPAL DISPLAY PANEL- 200 mg 100 ct Bottle****VALUMEDS**

\*Compare to the active ingredient in **Advil®**

**IBUPROFEN**

**TABLETS USP, 200MG**

**PAIN RELIEVER/**

**FEVER REDUCER**

**(NSAID)**

**100**

**TABLETS**

**(COATED BROWN)**

**VALUMEDS**  
 \* Compare to the active ingredient in Advil®  
**IBUPROFEN**  
**TABLETS USP, 200MG**  
 PAIN RELIEVER/  
 FEVER REDUCER  
 (NSAID)  
**100 TABLETS**  
 (COATED BROWN)

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Drug Facts**  
**Active ingredient (in each tablet)** Ibuprofen 200 mg (NSAID); Pain reliever/fever reducer  
**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 redness ■ 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 thinner (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

(continued under label)  
 Distributed By: Spirit Pharmaceuticals, LLC  
 Ronkonkoma, NY 11779 ORIG 04/17  
 ITEM# 941-01

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**Drug Facts (continued)**  
**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  
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 ■ 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)  
**Inactive ingredients** Colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide.  
**Questions or comments? 1-888-333-9792**  
 This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Advil®.

**VALUMEDS IBUPROFEN**

ibuprofen tablet, film coated

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0800
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	114
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0800-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2017	
2	NDC:68210-0800-4	1 in 1 CARTON	04/11/2018	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:68210-0800-3	1 in 1 CARTON	04/11/2018	
3		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	ANDA091239	05/19/2017	

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

## Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(68210-0800)

Revised: 9/2019

SPIRIT PHARMACEUTICALS LLC