

IBUPROFEN- ibuprofen tablet, film coated
Spirit Pharmaceuticals LLC

Ibuprofen

Drug Facts

Active Ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)**

**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 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

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

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: • chest pain • trouble breathing • weakness in one part or side of body • slurred speech • leg swelling • 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 • 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, corn starch, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, povidone K-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide, triacetin

Questions or comments?

1-888-333-9792

Principal Display Panel

Compare to Advil® Tablets active ingredient
ibuprofen

Ibuprofen Tablets, 200 mg

Pain Reliever / Fever Reducer (NSAID)

30 tablets

Drug Facts (continued)

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- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription and nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
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Questions or comments? 1-888-333-9792

VALUHEALTH
BY SPIRIT

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

30 tablets

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

KEEP OUTER CARTON FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION S

Active ingredient
(in each tablet)
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*nonsteroidal anti-inflammatory drug

Purpose

Uses

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 - muscular aches
 - minor pain of arthritis
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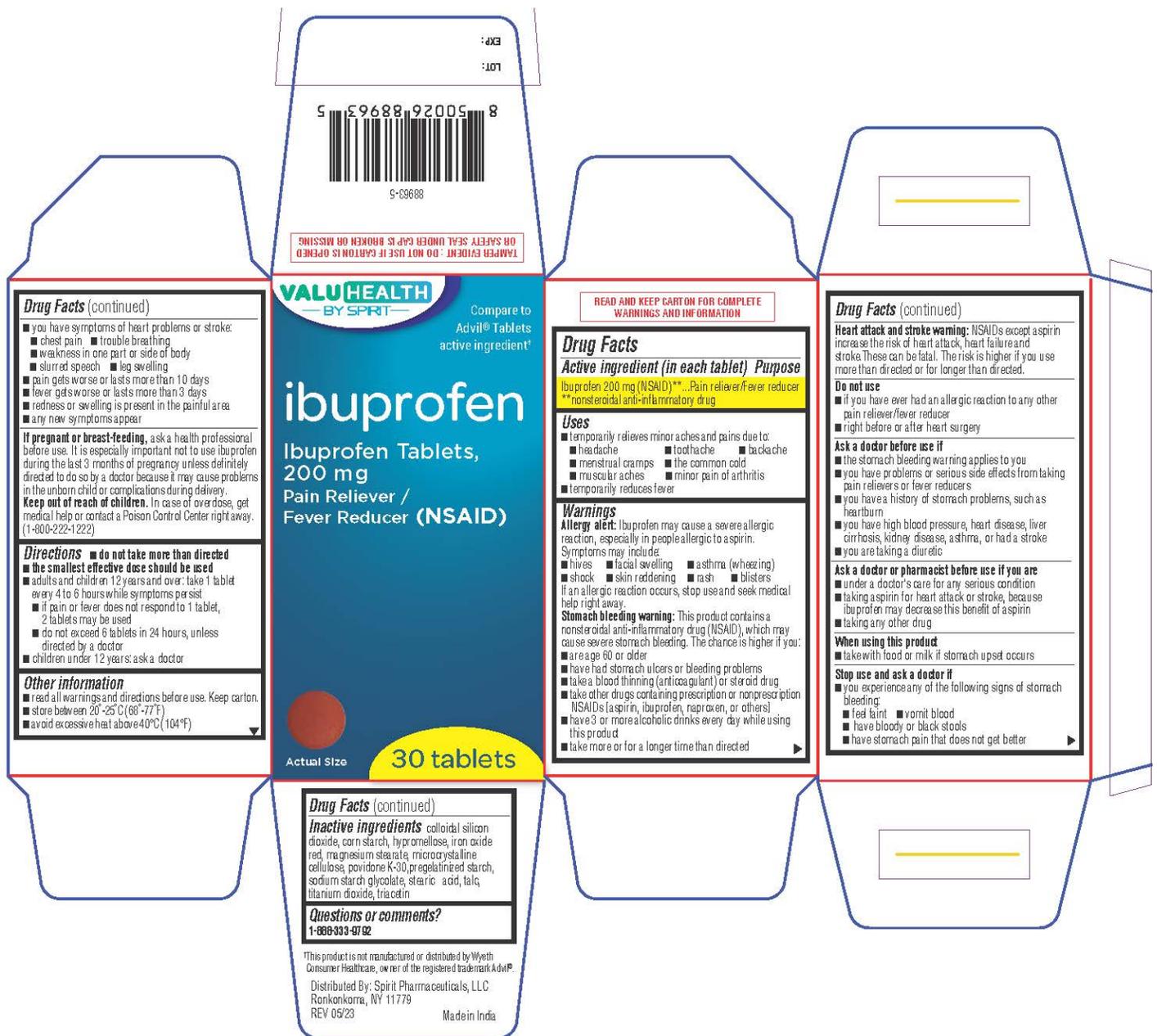
 If an allergic reaction occurs, stop use and seek medical help right away.

Drug Facts (continued under label)

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

Made in India

LOT: 88914-7
EXP:



IBUPROFEN

ibuprofen tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:68210-4199 |
| 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

Drug Facts (continued)

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This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Advil®.
Distributed By: Spirit Pharmaceuticals, LLC
Ronkonkoma, NY 11779
REV 05/23
Made in India

Drug Facts (continued)

- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling
- pain gets worse or lasts more than 10 days
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VALUHEALTH BY SPIRIT

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ibuprofen

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

Actual Size

30 tablets

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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**nonsteroidal anti-inflammatory drug

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Drug Facts (continued)

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- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
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 - feel faint
 - vomit blood
 - have bloody or black stools
- have stomach pain that does not get better

| Ingredient Name | Strength |
|---|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| TALC (UNII: 7SEV7J4R1U) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | brown | Score | no score |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | IBU;200 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:68210-4199-3 | 1 in 1 CARTON | 06/15/2022 | |
| 1 | | 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 | ANDA079129 | 06/15/2022 | |

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2024

Spirit Pharmaceuticals LLC