

ASSURED IBUPROFEN- ibuprofen tablet
Spirit Pharmaceuticals LLC

Assured Ibuprofen 40 ct

Drug Facts

Drug Facts

Active ingredient
(in each caplet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pain 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

Drug Facts (continued)

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 ibuprofen or 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
- 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
- you have symptoms of heart problems or stroke:

Drug Facts (continued)

- chest pain → trouble breathing

- ↪ leg swelling ↪ slurred speech
- ↪ weakness in one part or side of body
- ↪ 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**
- ↪ do not take longer than 10 days, unless directed by a doctor (see Warnings)
- ↪ adults and children 12 years and over: take 1 caplet every 4 to 6 hours while symptoms persist
- ↪ if pain or fever does not respond to 1 caplet, 2 caplets may be used
- ↪ do not exceed 6 caplets 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)

Drug Facts (continued)

Inactive ingredients

colloidal silicon dioxide, FD&C Yellow #6, hypromellose, maize starch, polydextrose, polyethylene glycol, povidone k30, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide.

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

ASSURED IBUPROFEN

Compare to active ingredient in Motrin® IB CAPLETS †

NDC 68210-0011-4

Ibuprofen

• **Ibuprofen Tablets USP, 200 mg**

Pain Reliever/Fever Reducer (NSAID)

Actual Size

40 Caplets

†This product is not manufactured or distributed
by Johnson & Johnson Corporation, owner of the
registered trademark Motrin® IB Caplets

ASSURED IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-0011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-0011-4	1 in 1 CARTON	02/25/2019	
1		40 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	ANDA202312	02/25/2019	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India LTD.		918609236	manufacture(68210-0011)

Revised: 12/2020

Spirit Pharmaceuticals LLC