

IBUPROFEN IMMEDIATE RELEASE- ibuprofen tablet, coated
Strides Pharma Inc

Ibuprofen Tablets USP, 200 mg
Drug Facts

Important: Read all product information before using.
Keep the box for important information.

Active ingredient (in each Brown tablet or caplet**)

Ibuprofen 200 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

**capsule-shaped tablets

Purpose

Pain reliever / fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - minor pain of arthritis
 - toothache
 - backache
 - the common cold
 - menstrual cramps
- 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 an 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 ibuprofen or any other pain reliever / fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- the stomach bleeding warning applies to you
- 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

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- 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 at 20 weeks or later in 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 older	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ ask a doctor

Other Information

- store between 20-25⁰C (68-77⁰F)
- **do not use if carton is opened. Do not use if foil inner seal imprinted with "Sealed For Your Safety" is broken or missing**

Inactive Ingredients

colloidal silicon dioxide, corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide and triacetin

Questions or Comments?

Call **1-855-742-7868** (toll-free)

Manufactured by:

Strides Pharma Science Limited,

Puducherry - 605 014, India.

Distributed by:

Strides Pharma Inc.

East Brunswick, NJ 08816

January 2022

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ibuprofen Tablets [200mg][Round-Brown][10,000's]
Sprit-US
Shipper Label

**PRODUCT: Ibuprofen Tablets USP 200mg [FC] [Round – Brown][10,000's]
[Sprit – US]**

NDC : 59556 – 857 – 42

QTY :

BATCH No.:

MFG date :

EXP date :

Storage Condition : Store between 20 – 25°C (68 – 77°F).

Shipper No.:

IBUPROFEN IMMEDIATE RELEASE

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59556-857
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRACETIN (UNII: XHX3C3X673)	
TALC (UNII: 7SEV7J4R1U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	BROWN	Score	no score
Shape	ROUND (Round shaped)	Size	10mm
Flavor		Imprint Code	IBU200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59556-857-42	10000 in 1 BAG; Type 0: Not a Combination Product	03/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	03/18/2022	

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SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

Product Characteristics

Color	BROWN	Score	no score
Shape	CAPSULE (capsule shaped)	Size	14mm
Flavor		Imprint Code	IBU200
Contains			

Packaging

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Labeler - Strides Pharma Inc (078868278)

