

**IBUPROFEN IMMEDIATE RELEASE- ibuprofen tablet, coated**  
**Strides Pharma Inc**

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**Ibuprofen Tablets USP, 200 mg**  
**Drug Facts**

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

***Active ingredient (in each Orange 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"> <li>▪ take 1 tablet every 4 to 6 hours while symptoms persist</li> <li>▪ if pain or fever does not respond to 1 tablet, 2 tablets may be used</li> <li>▪ do not exceed 6 tablets in 24 hours, unless directed by a doctor</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>▪ ask a doctor</li> </ul>

**Other Information**

- store between 20-25<sup>0</sup>C (68-77<sup>0</sup>F)
- **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, D&C yellow no.10 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, talc, titanium dioxide, and triacetin

**Questions or Comments**

Call **1-877-244-9825** (toll-free)

Manufactured by:

**Strides Pharma Science Limited,**

Puducherry - 605 014, India.

PON/DRUGS/16 13 4193

Distributed by:

**Strides Pharma Inc.**

East Brunswick, NJ 08816

January 2022

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

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

**PRODUCT: Ibuprofen Tablets USP 200mg [FC] [Caplet – Orange][OTC]  
[Sprit – US]**

**NDC : 59556 – 856 – 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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59556-855
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRACETIN</b> (UNII: XHX3C3X673)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	ROUND (Round shaped)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	IBU200
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59556-855-42	10000 in 1 BAG; Type 0: Not a Combination Product	03/18/2022	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA091355	03/18/2022	

# IBUPROFEN IMMEDIATE RELEASE

ibuprofen tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59556-856
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

## Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (capsule shaped)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	IBU200
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59556-856-42	10000 in 1 BAG; Type 0: Not a Combination Product	03/18/2022	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA091355	03/18/2022	

**Labeler** - Strides Pharma Inc (078868278)

**Registrant** - Strides Pharma Global Pte. Ltd. (659220961)

### Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		871402375	ANALYSIS(59556-855, 59556-856) , MANUFACTURE(59556-855, 59556-856) , PACK(59556-855, 59556-856)

### Establishment

Name	Address	ID/FEI	Business Operations
Vivimed Life Sciences Private Limited		860477684	ANALYSIS(59556-855, 59556-856) , MANUFACTURE(59556-855, 59556-856) , PACK(59556-855, 59556-856)

Revised: 4/2023

Strides Pharma Inc