

## **IBUPROFEN- ibuprofen tablet BI-MART**

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### **Ibuprofen Caplets, 200 mg**

#### ***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 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 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 any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- 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 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 (1-800-222-1222) right away.

**Directions**

- **do not take more than directed**
- **the smallest effective dose should be used**

<b>adults and children 12 years and over</b>	<ul style="list-style-type: none"> <li>• take 1 caplet every 4 to 6 hours while symptoms persist</li> <li>• if pain or fever does not respond to 1 caplet, 2 caplets may be used</li> <li>• do not exceed 6 caplets in 24 hours, unless directed by a doctor</li> </ul>
<b>children under 12 years</b>	<ul style="list-style-type: none"> <li>• ask a doctor</li> </ul>

**Other Information**

- store between 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)
- DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

**Inactive ingredients**

colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Questions?**

Call toll-free **1-844-912-4012:**



<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HFI6D95)	

### Product Characteristics

<b>Color</b>	red (Reddish Brown)	<b>Score</b>	no score
<b>Shape</b>	OVAL (capsule shaped tablet)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	G;2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37835-585-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	02/01/2025	

**Labeler** - BI-MART (027630078)

**Registrant** - BI-MART (027630078)

### Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(37835-585)

Revised: 2/2025

BI-MART