

**IBUPROFEN IMMEDIATE RELEASE- ibuprofen tablet, coated**  
**Discount Drug Mart**

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**Ibuprofen tablets USP 200mg**  
**Discount Drug Mart**

**Drug Facts**

**ACTIVE INGREDIENT(S)**

**(in each brown caplet)**

Ibuprofen USP 200 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

**PURPOSE**

Pain reliever/fever reducer

**USE(S)**

- 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 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

#### **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**

- 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, or kidney disease
- you have asthma
- you are taking a diuretic

#### **ASK A DOCTOR OR PHARMACIST BEFORE USE IF**

- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

#### **STOP USE AND ASK 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
- 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 (1-800-222-1222) right away.

## 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 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>
children under 12 years	<ul style="list-style-type: none"><li>• ask a doctor</li></ul>

## OTHER INFORMATION

- store between 20 – 25°C (68-77°F)
- **tamper evident:** do not use if imprinted safety seal under cap is broken or missing
- see end panel for lot number and expiry date

## INACTIVE INGREDIENT (S)

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

## QUESTIONS OR COMMENTS?

Adverse drug event Call: (877) 586-7979

## PRINCIPAL DISPLAY PANEL

Package Label (Capsule Shaped Tablets) - Principal Display Panel - 50s - Count Carton, 200 mg Tablets

DISCOUNT

drug mart

FOOD FAIR

NDC 53943-403-23

*SEE NEW WARNINGS INFORMATION*

*IBUPROFEN*

TABLETS, USP 200 mg

Pain Reliever / Fever Reducer (NSAID)\*

IBU

200

*50 COATED CAPLETS\*\**

\*nonsteroidal anti-inflammatory drug

\*\*capsule-shaped tablets

Compare to the Active Ingredient of ADVIL@\*\*\*

\*\*\*This product is not manufactured or distributed by Pfizer Inc. owner of the registered trade mark Advil@



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
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OPIR32D61U)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2910 (6 MPAS) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
TALC (UNII: 7SEV7J4R1U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

### Product Characteristics

Color	BROWN	Score	no score
Shape	CAPSULE (CAPSULE SHAPED)	Size	10mm
Flavor		Imprint Code	IBU200
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-403-23	1 in 1 CARTON		
1		50 in 1 BOTTLE		
2	NDC:53943-403-24	1 in 1 CARTON		
2		100 in 1 BOTTLE		
3	NDC:53943-403-29	500 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	12/22/2014	

Labeler - Discount Drug Mart (047741335)

Registrant - Shasun Pharmaceuticals Limited (915786829)

## Establishment

Name	Address	ID/FEI	Business Operations
Shasun Pharmaceuticals Limited		915786829	MANUFACTURE(53943-403)

Revised: 11/2014

Discount Drug Mart