

IBUPROFEN - ibuprofen tablet
Discount Drug Mart

ACTIVE INGREDIENT(S)

Ibuprofen 200 mg (NSAID)*

- Non-steroidal anti-inflammatory drug

PURPOSE

Pain reliever / fever reducer

USE(S)

- temporarily relieves minor aches and pain due to :
- backache
- headache
- menstrual cramps
- minor pain of arthritis
- muscular aches
- the common cold
- toothache
- temporarily reduces fever

WARNINGS

Allergy alerts: Ibuprofen may cause a severe allergy reaction, especially in people allergic to aspirin.

Symptoms may include:

- asthma (wheezing)
- blisters
- facial swelling
- hives
- rash
- shock
- skin reddening

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 stomach bleeding. The chance is higher if you:

- are age 60 or older
- have bad stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drug containing prescription NSAID (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- the 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
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- high blood pressure
- heart or kidney disease
- taken a diuretics
- reached age 60 or older

ASK A DOCTOR OR PHARMACIST BEFORE USE IF

You are

- taking any other drugs containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any serious condition
- taking aspirin for heart attacks 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
- long term continuous use may increase the risk of heart attack or stroke

STOP USE AND ASK DOCTOR IF

- You feel faint, vomit blood, or have bloody or black stools.

These are signs of stomach bleeding.

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- stomach pain or upset gets worse or lasts
- redness or swelling is present in painful area
- any new symptoms appear

PREGNANCY/BREASTFEEDING

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 a 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 PoisonControlCenter right away.

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 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

STORAGE

- Store between 20-25 0c (68-77 0 F).
- **do not use if seal under bottle cap imprinted with” SEALED for YOUR PROTECTION” is broken or missing.**

INACTIVE INGREDIENTS

Microcrystalline cellulose, Croscarmellose Sodium, Pregelatinized starch, Talc, Colloidal Silicon Dioxide, Magnesium stearate, polyethylene glycol, polyvinyl alcohol, titanium dioxide.

PRINCIPAL DISPLAY PANEL

Carton Label PDP

Drug mart
IBUPROFEN TABLETS, USP 200 mg
Pain Reliever/ Fever Reducer (NSAID)

100 COATED TABLETS



DYE-FREE

SEE NEW WARNINGS INFORMATION

IBUPROFEN

TABLETS, USP 200 mg
Pain Reliever /
Fever Reducer (NSAID)

100 COATED TABLETS

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THE BOX FOR IMPORTANT INFORMATION.

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

Purpose
(in each tablet)
Ibuprofen 200 mg (NSAID)..... Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - backache
 - headache
 - menstrual cramps
 - minor pain of arthritis
 - muscular aches
 - the common cold
 - toothache
- temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- asthma (wheezing)
- diarrhea
- facial swelling
- hives
- rash
- shock
- skin redness

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 thinner (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

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
- 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. Keep out of reach of children.

Directions

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

Adults and children 12 years and older:

- 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

Other information

- store between 20°-25°C (68°-77°F)
- do not use if seal under cap is broken or missing

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Distributed By: DRUG MART-FOOD FAIR
MEDINA, OHIO 44256

LOT:
EXP:

Iss: 06/13

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53943-115
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-115-01	1 in 1 CARTON		
1		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091237	06/20/2013	

Labeler - Discount Drug Mart (047741335)**Registrant** - Discount Drug Mart (047741335)**Establishment**

Name	Address	ID/FEI	Business Operations
Marksans Pharma Limited		925822975	MANUFACTURE(53943-115)

Revised: 6/2013

Discount Drug Mart