

IBUPROFEN - ibuprofen tablet
Apotheca Inc.

Ibuprofen Tablets, USP (NSAID) Pain Reliever/ Fever Reducer DRUG FACTS

ACTIVE INGREDIENT

(in each Tablet)

Ibuprofen 200 mg (NSAID)**

**nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USES

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- minor pain or 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.

Alcohol Warning: If you consume 3 or more alcohol drinks per day, ask your Doctor whether you should take Ibuprofen or other pain relievers/fever reducers.

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 had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing NSAID (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 DOCTOR

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 diuretic**
- **reached age 60 or older**

Ask a doctor before use if you are

- **taking aspirin for heart attack or stroke because ibuprofen may decrease this benefit of aspirin**
- **taking any other drug containing an NSAID (prescription or nonprescription)**
- **taking a blood thinning (anticoagulant) or steroid drug**
- **under a doctor's care for any serious condition**
- **taking any other drug**
- **consuming 3 or more alcohol drinks per day**

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 A 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 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 **1-800-362-0101** (Arizona only) immediately.

DIRECTIONS

- 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 caplet every 4 to 6 hours while symptoms persist• if pain or fever does not respond to 1 caplet, 2 caplets may be used• do not exceed 6 caplets in a 24-hour period, unless directed by a physician• take with food or milk, if occasional and mild heartburn, upset stomach, or stomach pain occurs with use• consult a physician if these symptoms are more than mild or if they persist
Children under 12 years	<ul style="list-style-type: none">• not for use

OTHER INFORMATION

Other information

- store at 15 – 30°C (59-86°F).

Inactive ingredients

Anhydrous Lactose, Carnauba Wax, Colloidal Silicon Dioxide, Hypromellose, Iron Oxide Red, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Povidone, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Corn Starch, Titanium Dioxide.

QUESTIONS OR COMMENTS

Call 1-800-262-5244

Monday through Friday 9AM – 2PM MST

Distributed by:

RejuviLife, Phoenix, AZ

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PACKAGE LABEL, PRINCIPAL DISPLAY PANEL, ADDITIONAL LABELS UPON REQUEST

NDC 12634-860-01

IBUPROFEN

**MAXIMUM STRENGTH
WITHOUT A PRESCRIPTION**

*Pain Reliever
Fever Reducer*

RejuviLife®

100 CAPLETS

200 MG

NDC 12634-860-01



MAXIMUM STRENGTH
WITHOUT A PRESCRIPTION

Pain Reliever
Fever Reducer



100 CAPLETS • 200 MG

Store at 15° to 30° C (59° to 86° F)

Drug Facts

Active ingredient (in each caplet)
Ibuprofen 200 mg (NSAID)
*nonsteroidal anti-inflammatory drug

Purpose
Pain & Fever Reliever

Uses
For the temporary relief of minor aches and pains associated with the common cold, headache, neurache, muscular aches, backache, for the minor pain of arthritis, for the pain of menstrual cramps and for the reduction of fever.

Warnings
ASPIRIN SENSITIVE PATIENTS: Do not take this product if you have had a severe allergic reaction to aspirin, e.g. asthma, swelling, shock or hives because even though this product contains no aspirin or salicylates, cross reaction may occur in patients allergic to aspirin. Do not take for pain for more than 10 days or for fever for more than 3 days unless directed by a physician. If pain or fever persists, or gets worse, or if new symptoms occur, or if the painless one is used or worsens, consult a physician, as these could be signs of a serious illness. If you are under a physician's care for any serious condition, consult a physician before taking this product.

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 had stomach ulcers or bleeding problems, take a blood thinner (anticoagulant) or several drug-tablet combinations (NSAID) together, have kidney or liver problems, or take other drugs that may increase the risk of stomach bleeding.

Ask a doctor before use if you have: problems or serious side effects from taking any pain reliever in the previous 3 months; problems that last or come back, such as heartburn, upset stomach, or stomach pain; ulcers or bleeding problems; high blood pressure; heart or kidney disease; history of liver or kidney problems; or if you are 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 absolutely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

IF YOU EXPERIENCE ANY SYMPTOMS WHICH ARE UNUSUAL OR SEEM UNRELATED TO THE CONDITION FOR WHICH YOU TOOK IBUPROFEN, CONSULT A PHYSICIAN BEFORE TAKING ANY MORE OF IT.

Alcohol Warning: In case of accidental overdose, seek medical help or contact a Poison Control Center immediately. Toll free: 1-800-362-6101 (Arizona only). Keep out of reach of children.

Directions
1 caplet every 4 to 6 hours. While symptoms persist, do not exceed 6 caplets in 24 hours unless directed by a physician. The smallest effective dose should be used. Take with food or milk if occasional and mild heartburn, upset stomach, or stomach pain occurs with use. Consult a physician if these symptoms are more than mild or if they persist.

Other information
Keep this use in children under 12 years of age.
Inactive ingredients: Anhydrous Lactose, Croscarmellose, Cellulose, Silicon Dioxide, Carnauba Wax, Colloidal Silicon Dioxide, Croscarmellose, Iron Oxide Red, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Prevalar, Sodium Lauryl Sulfate, Sodium Starch Glycolate, Titanium Dioxide.

EXP. DATE:
LOT #:
Dist. by RejuviliLife, Phoenix, AZ
DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN OR MISSING.
7 93522 18600 1 15

IBUPROFEN			
ibuprofen tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12634-860(NDC:53746-142)
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
ANHYDROUS LACTOSE (UNII: 3S Y5LH9 PMK)			
CARNAUBA WAX (UNII: R12CBM0 EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6 XBU4)			
HYPROMELLOSE (UNII: 3NXW29 V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6 I3O)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6 1U)			
POVIDONE (UNII: FZ989GH9 4E)			
SODIUM LAURYL SULFATE (UNII: 368GB514J)			
STARCH, CORN (UNII: O8232NY3SJ)			
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP)			

Product Characteristics

Color	brown (BROWN)	Score	no score
Shape	OVAL (CAPSULE-SHAPE)	Size	13mm
Flavor		Imprint Code	IP;142
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12634-860-24	24 in 1 BOTTLE, PLASTIC		
2	NDC:12634-860-01	100 in 1 BOTTLE, PLASTIC		
3	NDC:12634-860-10	1000 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA071333	09/16/2009	

Labeler - Apotheca Inc. (051457844)

Establishment

Name	Address	ID/FEI	Business Operations
Apotheca Inc.		051457844	relabel, repack

Revised: 2/2010

Apotheca Inc.