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 ay 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

- d**o not take longer than 10 days, unless directed by a doctor (see Warnings)**

Adults and children 12 years and older	• 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 thsn mild or if they persist
Children under 12 years	• 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 though Friday 9AM – 2PM MST

Distributed by:

RejuviLife, Phoenix, AZ

RejuviLife is a trademark of Apotheca Inc.

PACKAGE LABEL,PRINCIPAL DISPLAY PANEL,ADDITIONAL LABELS UPON REQUEST

NDC 12634-860-01

IBUPROFEN

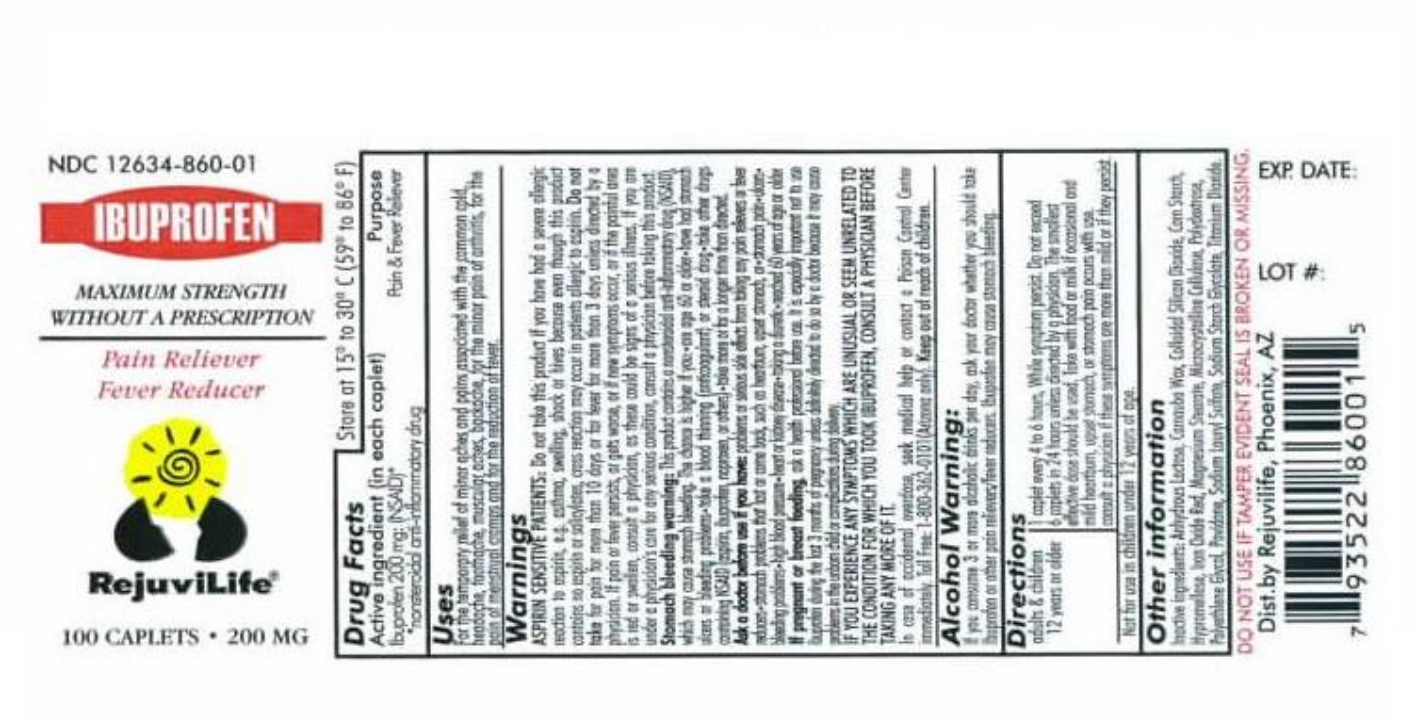
MAXIMUM STRENGTH
WITHOUT A PRESCRIPTION

Pain Reliever
Fever Reducer

RejuviLife®

100 CAPLETS

200 MG



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: 3SY5LH9PMK)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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.