

IBUPROFEN - ibuprofen tablet
Apotheca, Inc

Ibuprofen Tablets, USP 200mg (NSAID)

ACTIVE INGREDIENT

Ibuprofen 200 mg (NSAID)*

* nonstreoidal 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 DOCTOR/PHARMACIST

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 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 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. (1-800-222-1222)

INACTIVE INGREDIENTS

colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline

cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinised starch, talc, titanium dioxide.

QUESTIONS

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

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.

Children under 12 years

- ask a doctor
-

Other information

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**

PRINCIPAL DISPLAY PANEL

Manufactured for:

Marksans Pharma Inc.
Lake Grove, NY11755, USA

Manufactured by:

Marksans Pharma Ltd.
Verna, Goa-403722, India

Repackaged and Distributed by:

Apotheca, Inc.
Phoenix, AZ 85006

Repackaged and Distributed for:

RejuviLife

Phoenix, AZ 85015

NDC 12634-518-74

IBUPROFEN

MAXIMUM STRENGTH

WITHOUT A PRESCRIPTION

BROWN COATED TABLETS

Pain Reliever

Fever Reducer

RejuviLife®

24 TABLETS 200MG

NDC 12634-518-74

IBUPROFEN

MAXIMUM STRENGTH
WITHOUT A PRESCRIPTION
BROWN COATED TABLETS

*Pain Reliever
Fever Reducer*



RejuviLife®

24 TABLETS • 200 MG

Drug Facts
Active ingredient (in each tablet) Ibuprofen 200 mg (NSAID).....Pain reliever/fever reducer/nonsteroidal anti-inflammatory drug.

Purpose
Ibuprofen temporarily relieves minor aches and pains due to:
• headaches • muscular aches • minor pain of arthritis • toothache • backache
• the common cold • menstrual cramps • temporarily reduces fever

Warnings: Allergy alert: Ibuprofen may cause severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
• hives • facial swelling • asthma (breathing) • shock • rash • hiccups
• skin redness • 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 and older • have had stomach ulcers or bleeding problems • take a blood thinning (anticoagulant) or stomach drug • take other drugs containing an NSAID (aspirin, naproxen, paracetamol, or others) • have 3 or more alcoholic drinks a day while using this product, take more or for longer time than directed.

Do not use if you have had an allergic reaction to any other pain reliever/fever reducer • right before or after surgery

Ask doctor or pharmacist before use if you are:
• under 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 • the 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 problems or kidney disease or asthma • you are taking a diuretic, anticoagulant or stomach drug continuously use may increase the risk of heart attack or stroke.

When taking 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 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 • allergic reaction occurs • pain gets worse or last more than 10 days • weakness or swelling is present • any new symptoms occur • swelling in legs or loss of hearing occurs. These could be signs of serious condition. • Fever gets worse or lasts more than 3 days.

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 directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. **Keep out of the reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-272-1222).

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: Take one tablet every 4 to 6 hours while symptoms persist
• If pain or fever do not respond to 1 tablet, 2 tablets may be used • Do not exceed 6 tablets in 24 hours unless directed by a physician • Children under 12 years old: ask doctor

Other information: • Store at room temperature • Avoid excessive heat above 40°C (104°F)
• To report adverse drug events, call 1-800-332-1088

Inactive ingredients: Colloidal silicon dioxide, croscarmellose sodium, iron oxide red, microcrystalline cellulose, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, TBC, titanium dioxide

DO NOT USE IF TAMPER EVIDENT SEAL IS BROKEN OR MISSING.
Dist. by RejuviLife, Phoenix, AZ **LOT. EXP.**



IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:12634-518(NDC:25000-114)
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
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12634-518-74	24 in 1 BOTTLE		
2	NDC:12634-518-01	100 in 1 BOTTLE		
3	NDC:12634-518-10	1000 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	02/14/2014	

Labeler - Apothea, Inc (051457844)

Establishment

Name	Address	ID/FEI	Business Operations
Apothea, Inc		051457844	repack(12634-518)

Revised: 3/2014

Apothea, Inc