

**IBUPROFEN - ibuprofen tablet**  
**Polygen Pharmaceuticals LLC**

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**ACTIVE INGREDIENT(S)**

(each Caplet contains)

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"> <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>

### STORAGE

- Store between 20-25<sup>0</sup>C (68-77<sup>0</sup>F).
- **do not use if seal under bottle cap is broken or missing.**

### INACTIVE INGREDIENTS

Microcrystalline Cellulose, Croscarmellose Sodium, Pregelatinized starch, talc, Colloidal silicon dioxide, Magnesium stearate, polyvinyl Alcohol, Polyethylene glycol, Titanium dioxide.

### PRINCIPAL DISPLAY PANEL

**Carton Label**

**Thrulife**

**NDC : 52605-120-01**

**IBUPROFEN TABLETS, 200 mg**

**PAIN RELIEVER/ FEVER REDUCER (NSAID)**

**100 COATED CAPLETS**

**CAPSULE SHAPED TABLETS**



# IBUPROFEN

ibuprofen tablet

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52605-120
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
COLLOIDAL SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	120
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52605-120-01	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	07/02/2013	

**Labeler** - Polygen Pharmaceuticals LLC (962415720)

**Registrant** - Polygen Pharmaceuticals LLC (962415720)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Marksans Pharma Limited		925822975	MANUFACTURE(52605-120)

Revised: 7/2013

Polygen Pharmaceuticals LLC