

**IBUPROFEN- ibuprofen tablet, film coated
DIRECT RX**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

IBUPROFEN

OTC - ACTIVE INGREDIENT SECTION

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

OTC - PURPOSE SECTION

Pain reliever/fever reducer

INDICATIONS & USAGE SECTION

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

WARNINGS SECTION

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.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- have had stomach ulcers or bleeding problems
- take a blood thinning (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

- right before or after heart surgery
- if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- taking any other drug
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - 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. 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 right away.

OTC - KEEP OUT OF REACH OF CHILDREN SECTION

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facial swelling

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Ask a doctor or pharmacist before use if you are taking any other drug

taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin under a doctor's care for any serious condition

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OTC - WHEN USING SECTION

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: 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

INFORMATION FOR PATIENTS SECTION

- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)
- use by expiration date on package

DOSAGE & ADMINISTRATION SECTION

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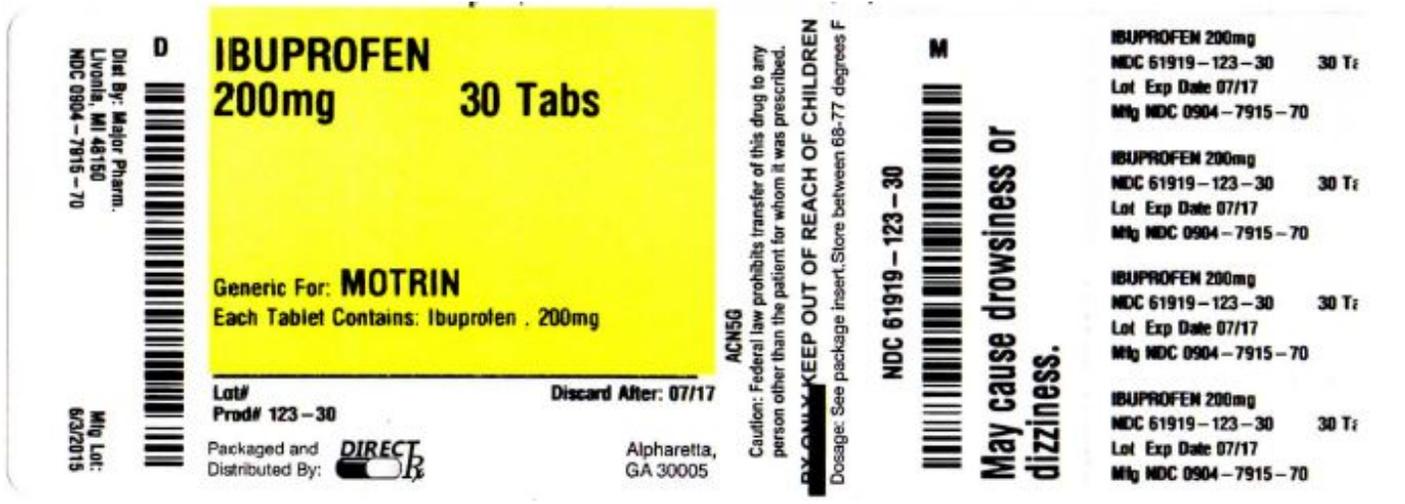
INACTIVE INGREDIENT SECTION

carnauba wax, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

OTC - QUESTIONS SECTION

(800) 616-2471

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61919-123(NDC:0904-7915)
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
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10 mm
Flavor		Imprint Code	44;291
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-123-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/2014	

Labeler - DIRECT RX (079254320)

Establishment			
Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	relabel(61919-123) , repack(61919-123)

Revised: 11/2015

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