

IBUPROFEN- ibuprofen tablet, film coated
Raining Rose Inc.

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 - 0412

Drug Facts

Active ingredient

Active ingredient (in each tablet)

Ibuprofen (NSAID)* 200 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Keep out of reach of children

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Uses

• Temporarily relieves minor aches and pains associated with • headache • toothache • backache • menstrual cramps • common cold • muscular aches • minor arthritis pain • Temporarily reduces fever.

Warnings Allergy Alert:

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

• hives • skin reddening • facial swelling • rash • asthma (wheezing) • blister • shock 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: • are age 60 or older • have had stomach ulcers or bleeding problems • take a blood thinner (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

• 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

• 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 problems or serious side effects from taking pain relievers or fever reducers • you have asthma

Ask a doctor or pharmacist before use if you are

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

When using this product

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

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 • 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 or unexpected 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 specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Directions

• **do not use more than directed • the smallest effective dose should be used** • 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: Do not give to children under 12 years of age.

Inactive ingredients:

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.

Other Information

• read all product information before using.

Store at 68-77°F (20-25°C) • Avoid excessive heat, above 104°F (40°C).

Ibuprofen product label

IBUPROFEN

12 Ibuprofen Tablets USP, 200 mg Pain Reliever/Fever Reducer (NSAID)

LOT CODE:

EXP DATE:

OPEN HERE TO VIEW COMPLETE PRODUCT INFORMATION

Do not use if safety seal is broken.

TAMPER EVIDENT: DO NOT USE IF THIS SAFETY SEAL AROUND CAP IS BROKEN OR MISSING

TEAR HERE TO OPEN

Dist. By Raining Rose, Inc. Cedar Rapids, IA 52403

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✓ OPEN HERE TO VIEW COMPLETE PRODUCT INFORMATION
Do not use if safety seal is broken.

IMPRINT AREA

Ibuprofen

12 Ibuprofen Tablets USP, 200 mg
Pain Reliever/Fever Reducer (NSAID)

LOT CODE:

EXP DATE:

Drug Facts

Active Ingredient (in each tablet)	Purpose
Ibuprofen (NSAID*) 200mg	Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug	

Uses - Temporarily relieves minor aches and pains associated with
• headache • toothache • backache • menstrual cramps • common
cold • muscular aches • minor arthritis pain. Temporarily reduces fever.

Warnings • **Allergy alert:** Ibuprofen may cause a severe allergic
reaction, especially in people allergic to aspirin. Symptoms may
include: • hives • skin reddening • facial swelling • rash • asthma
(wheezing) • blister • shock. If an allergic reaction occurs, stop use and
seek medical help right away. **Stomach bleeding warning:** This

OVERLAPPED AREA

TAMPER EVIDENT: DO NOT USE IF THIS SAFETY SEAL AROUND CAP IS BROKEN OR MISSING
TEAR HERE TO OPEN

product contains an NSAID, which may cause severe 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 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** • 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** • 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 problems or serious side effects from taking pain relievers or fever reducers • you have asthma. **Ask a doctor or pharmacist before use if you are** • taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit or aspirin • taking any other drug • under a doctor's care for any serious condition. **When using this product** • the risk of heart attack or stroke may increase if you use more than directed or longer than directed • take with food or milk if stomach upset occurs. **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 • 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 or unexpected 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 specifically 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.

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Other information • read all product information before using. Store at 68-77°F (20-25°C) • Avoid excessive heat, above 104°F (40°C).

Inactive ingredients: 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.

Dist. by: Raining Rose, Inc. Cedar Rapids, IA 52403

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IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0412
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			
CARNAUBA WAX (UNII: R12CBM0EIZ)				
STARCH, CORN (UNII: O8232NY3SJ)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
LACTOSE (UNII: J2B2A4N98G)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	44;532	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0412-1	12 in 1 VIAL; Type 0: Not a Combination Product	08/01/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part343	08/01/2015		

Labeler - Raining Rose Inc. (083819404)

Registrant - Raining Rose Inc. (083819404)

Establishment

Name	Address	ID/FEI	Business Operations
Raining Rose Inc.		083819404	manufacture(65692-0412) , relabel(65692-0412) , repack(65692-0412)