

DIRECT SAFETY IBUPROFEN- ibuprofen tablet, coated
Conney Safety Products, LLC

Direct Safety Ibuprofen

Drug Facts

Active ingredient

Ibuprofen 200 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

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 ■ asthma (wheezing) ■ facial swelling ■ rash ■ shock ■ 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:

■ 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

Heart attack or stroke warning:

NSAIDS, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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

- you have problems or serious side effects from taking pain relievers or fever reducers
- 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 have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

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

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

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
- you have symptoms of heart problems or stroke

■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling

■ pain gets worse or lasts for more than 10 days

■ fever gets worse or lasts for more than 3 days

■ redness or swelling is present in the painful area

■ any new or unexpected symptoms occur

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.

Directions

■ **do not use 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 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.

Other information

■ read all product information before using

■ store at 68-77°F (20-25°C)

■ avoid excessive heat 40°C (above 104°F)

■ tamper evident sealed packets

■ do not use any opened or torn packets

Inactive ingredients

carnauba wax*, corn starch, hypromellose*, iron oxide red, lactose*, magnesium

**may contain*

1-800-356-9100

(250 Packets of 2 Tablets)

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61245-084
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	brown (REDDISH BROWN)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61245-084-13	250 in 1 BOX	11/17/2014	
1		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	11/17/2014	

Labeler - Conney Safety Products, LLC (023316151)

