

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

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**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 and 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 if**

- 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, kidney disease, asthma or had a stroke
- 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**

- 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 stearate\*, microcrystalline cellulose\*, polydextrose\*, polyethylene glycol, polyvinyl



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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
LACTOSE (UNII: J2B2A4N98G)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61245-085-13	250 in 1 BOX	02/01/2016	
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	ANDA075010	02/01/2016	

Labeler - Conney Safety Products, LLC (023316151)

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Conney Safety Products, LLC