

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 stearate*, microcrystalline cellulose*, polydextrose*, polyethylene glycol, polyvinyl alcohol*, povidone K30*, silicon dioxide, sodium starch glycolate, stearic acid, talc*, titanium dioxide

**may contain*

Questions or comments?

1-800-356-9100

Direct Safety Ibuprofen Label

Direct Safety®

Ibuprofen

Pain Reliever/Fever reducer

Ibuprofen 200 mg. (NSAID)

Ibuprofeno 200 mg. (AINE)

Lightly Coated

Pull To Open

Tire Para Abrir

Industrial Pack 500

(250 Packets of 2 Tablets)

DIRECTSAFETY

Drug Facts

Active ingredient (in each tablet) Ibuprofen 200 mg (NSAID) Purpose Pain reliever/fever reducer

Temporarily relieves minor aches and pains associated with: headache, toothache, common cold, muscular aches, minor arthritis pain.

Temporarily relieves fever.

Warnings: Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include hives, rash, difficulty breathing, facial swelling, dizziness, fainting, or loss of consciousness. Stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. You should stop using it if you have any of the following signs or symptoms: black or dark stools, blood in your stool, or blood in your urine.

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 are over 60, have heart disease, high blood pressure, or are taking aspirin for heart disease. Stop use and seek medical help right away if you experience any of the following symptoms: chest pain, shortness of breath, weakness in one part of your body, slurred speech, or difficulty seeing.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Ask a doctor before use if: you have problems or serious side effects from taking pain relievers or fever reducers; you have a history of stomach problems such as heartburn; you have high blood pressure, heart disease, liver disease, kidney disease, asthma, or are taking aspirin.

Ask a doctor or pharmacist before use if you are: taking aspirin for heart attack or stroke, because aspirin may decrease its benefit if taken; or taking any other drug.

DIRECTSAFETY

IBUPROFEN

Pain Reliever/ Fever Reducer

**Ibuprofen 200 mg. (NSAID)
Ibuprofeno 200 mg. (AINE)**

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. Do not use for more than 10 days, unless directed by a doctor. Do not use for longer than 10 days, unless directed by a doctor. Do not use for longer than 10 days, unless directed by a doctor. Do not use for longer than 10 days, unless directed by a doctor.

Other information: Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer. Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Questions or comments? 1-800-356-9100

DIRECTSAFETY

Información del medicamento

Ingrediente activo (en cada tableta) Ibuprofeno 200 mg (AINE) Propiedad Analgésico antiinflamatorio no esteroideo

Usos: Alivia temporalmente leves malestares y dolores a los que se les asocia con dolor de cabeza, dolor dentario, dolor de espalda, dolores menstruales, resfriado común, dolores musculares, fiebre debida a otras causas. Reduce la fiebre de manera temporal.

Advertencias: Alerta sobre las alergias: El ibuprofeno pudiera producir una severa reacción alérgica, sobre todo en personas que son alérgicas a la aspirina. Estas reacciones pueden incluir: erupción, hinchamiento de la piel, náusea (respiración con dificultad), hinchazón facial, angustia, shock, pérdida de conciencia.

Advertencia acerca del sangrado estomacal: Este producto contiene un medicamento antiinflamatorio no esteroideo (AINE), el cual puede causar sangrado estomacal. Las probabilidades de que ocurra esto aumentan si: tiene la edad de 65 años o más; si ha tenido úlceras estomacales o problemas de sangrado; si toma medicamentos para el adelgazamiento de la sangre (anticoagulantes) o esteroideos; si toma otros medicamentos, con o sin receta médica, que contengan un AINE (aspirina, ibuprofeno, naproxeno, etc.); si toma 3 o más bebidas alcohólicas diariamente mientras consume este producto; si se consume más de por más tiempo del indicado.

Advertencia de ataque al corazón o ataque cerebral: Los AINE, excepto la aspirina, incrementan el riesgo de un ataque al corazón, infarto de miocardio y un ataque cerebral. Esto puede ser fatal. El riesgo de morir se mantiene más o por más tiempo lo indicado.

No se aconseja: si ha experimentado alguna vez una reacción alérgica a cualquier otro producto que alivia el dolor/malestar de la fiebre.

Consulte con un médico antes de consumir si: si experimenta antes o después de una cirugía del corazón; si tiene antecedentes de problemas estomacales tales como dolor estomacal; si toma la presión sanguínea alta, enfermedad del corazón, enfermedad del hígado o enfermedad de los riñones, antes o luego de un ataque cerebral; si está tomando un diuretico; si experimenta problemas gástricos antes de administrarlo, si está estú; si está tomando aspirina a causa de un ataque al corazón o un ataque cerebral, ya que el ibuprofeno pudiera disminuir el beneficio de la aspirina; si toma cualquier otra medicina; si se encuentra bajo cuidado médico debido a un estado de salud grave.

Conservar la caja para obtener la información completa del producto

IBUPROFENO, ALIVIA EL DOLOR/REDUCE LA FIEBRE (AINE)

PAQUETES CON SELLADO EVIDENTE. NO USE NINGUN PAQUETE ABIERTO O ROTO.

Reader No. 23577
Reorder: 800-356-9100
coney.com

DIRECT SAFETY IBUPROFEN			
ibuprofen tablet, coated			
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: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)		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: U7250QWY32X)			
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)

Revised: 4/2019

Conney Safety Products, LLC