

COUNTERACT IB- ibuprofen tablet, coated
Melaleuca, Inc

CounterAct IB Content of Label

Purpose

Pain reliever/fever reducer

Uses

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

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
- the 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
- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug

When using this product

- take with food or milk if stomach upset occurs
- long term continuous use may increase the risk of heart attack or stroke

Stop use and ask a doctor if

- you experience any of the following signs of bleeding:
 - feel faint
 - vomit blood

- have blood 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 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 (1-800-222-1222).

Directions

- **do not take 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:
 - ask a doctor

Other information

- Store between 20 to 25°C (68 to 77°F)
- Read all warnings and directions before use
- save carton for complete drug facts information and warnings

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? call 1-800-282-3000

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



Take 3 or more alcoholic drinks every day while using this product. 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. Ask a doctor before use if you have stomach bleeding warning signs to you. Ask a doctor before use if you have heartburn, upset stomach, or stomach pain. Ask a doctor before use if you have high blood pressure, heart disease, kidney disease, ulcers, asthma, or bleeding problems. Ask a doctor before use if you are taking a diuretic. Ask a doctor before use if you are taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin. Ask a doctor before use if you are taking a blood thinning (anticoagulant) or steroid drug. Ask a doctor before use if you are taking any other drug. 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, vomit blood, bloody or black stools, stomach pain or upset gets worse or last, 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, or any new symptoms appear.



 Dist. by Melaleuca, Inc.

 14400 Falls, 10, US 5042

 1-800-282-3800

 #2252, Rev. 11/15 U

 NOT FOR RESALE

Drug Facts (continued)

Use during pregnancy: 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. (1-800-222-1222).

Directions: Do not take more than directed. The smallest effective dose should be used. Do not take longer than 10 days, unless directed by a doctor (see Warnings) in 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 3 tablets in 24 hours, unless directed by a doctor. Children under 12 years: ask a doctor.

Other information: Store at 15°-30°C (59°-86°F). Read all warnings and directions before use. Use carefully for complete drug facts information and warnings.

Inactive ingredients: calcium stearate, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide.

Questions or comments? call 1-800-282-3800



Melaleuca
CounterAct^{IB}
 Ibuprofen Tablets 200 mg
 Pain Reliever and Fever Reducer (NSAID)
 Nonprescription-Strength Medicine for Body Aches & Pains
 50 Coated Tablets (200 mg each)

Pain Reliever and Fever Reducer (NSAID)
 WARNING: STOP USE IF YOU EXPERIENCE STOMACH BLEEDING WARNING SIGNS

Drug Facts **RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION**

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

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

Warnings: **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 redness, or rash. **Children:** 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).

Medication

CounterAct[®] IB
Ibuprofen Tablets
200 mg

Pain Reliever and
Fever Reducer (NSAID)

50 Coated Tablets
(200 mg each)

NOT FOR RESALE

COMPLETE PATIENT INFORMATION	
Drug Facts	Purpose
Active ingredient (in each tablet) Ibuprofen 200 mg (NSAID)	Pain reliever/fever reducer NSAID and non-steroidal anti-inflammatory drug
Uses Ibuprofen temporarily relieves minor aches and pains (such as headache or backache) in nonhealed sprains or minor pain of arthritis. It temporarily relieves the common cold. It helps to temporarily reduce fever.	
Warnings Always check the label. Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: rash or hives; facial swelling; difficulty breathing; or shock. If you're having any rash or hives, if you develop wheezing, asthma, chest pain and seek medical help right away. Women: bleeding warning: This product contains an NSAID, which may cause serious stomach bleeding. The chance is higher if you're over age 60 or when you're taking other drugs or having problems with a blood thinner (anticoagulant) or alcohol. Do not take other drugs containing prescription or over-the-counter NSAIDs (aspirin, ibuprofen, naproxen, or others) at the same time unless your doctor tells you to. Do not use this product to take more or for a longer time than directed. If pregnant or breast-feeding, stop taking this medicine right away. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless directly advised to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Stop use at onset of labor. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-422-1222)	
Directions Do not take more than directed in the enclosed directions. Do not take for more than 10 days, unless directed by a doctor (see Warnings). Adults and children 12 years and older: take 1 tablet every 4-6 hours until symptoms subside. If pain or fever does not improve in 1 tablet, 2 tablets may be used to get relief. Do not exceed 6 tablets in 24 hours, unless directed by a doctor. Children under 12 years: ask a doctor.	
Other information See also at 15-017 (S1-017) in each of cartons and directions before use.	
1-800-282-3080	
DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING LMT1916	
<p>MADE BY: Medvet, Inc. MICHIGAN, U.S.A.</p> <p>© 2010 NDC: 54473-308</p>	

COUNTERACT IB

ibuprofen tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:54473-308

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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown (Brown)	Score	no score
Shape	ROUND (Round)	Size	10mm
Flavor		Imprint Code	114
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-308-50	1 in 1 BOX	08/15/2019	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091239	08/15/2019	

Labeler - Melaleuca, Inc (139760102)

Registrant - Melaleuca, Inc (139760102)

