

COUNTERACT IB- ibuprofen tablet, coated
Melaleuca, Inc

CounterAct IB Content of Label

Active Ingredient (in each tablet)

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

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

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 reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning:This product contains an nonsteroidal anti-inflammatory drug (NSAID), which may cause severe bleeding. The chances are 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

- 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

Carnuba Wax, Corn Starch, Fumed Silica Gel, Hypromellose, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Polydextrose, Polyethylene Glycol, Red Iron Oxide, Stearic Acid, Sodium Starch Glycolate, Titanium Dioxide

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

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

Drug Facts (continued)

■ 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 ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ the stomach bleeding warning applies to you ■ you have stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain ■ you have high blood pressure, liver cirrhosis, heart disease, or kidney disease, or ulcers

Ask a doctor or pharmacist before use if you are ■ under a doctor's care for any serious condition ■ taking aspirin for heart attack or strokes, because ibuprofen may decrease the benefit of aspirin ■ taking a blood thinning (anticoagulant) or steroid drug ■ 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 lasts ■ 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

Dist by: Melaleuca, Inc.
 Idaho Falls, ID 83402
 To order: 208-534-3000
 Melaleuca.com
 N° 252 0873 U
NOT FOR RESALE



Drug Facts (continued)

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) ■ 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 at 15°-30°C (59°-85°F); ■ read all warnings and directions before use ■ save carton for complete drug facts information and warnings

Inactive ingredients carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?
 Call 208-534-3000



Melaleuca
CounterAct[®] IB
Ibuprofen Tablets 200 mg
 Pain Reliever and Fever Reducer (NSAID)

WARNING: DO NOT USE IF SAFETY SEAL BROKEN OR IS MISSING

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)



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: ■ backache ■ headache ■ 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 reddening ■ rash ■ 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)



CounterAct[®] IB
Pain Reliever and Fever Reducer

READ AND RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

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

Uses ■ temporarily relieves minor aches and pains due to:
 ■ backache ■ headache ■ 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 reddening ■ rash ■ 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. **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)
adults and children 12 years and older: ■ take 1 tablet every 4 - 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 at 15°–30°C (59°–86°F)
 ■ read all warnings and directions before use.

1-800-282-3000

DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING

COUNTERACT IB

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-306
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
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown (Brown)	Score	no score
Shape	ROUND (Round)	Size	10mm
Flavor		Imprint Code	Ua;0001
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-306-50	1 in 1 BOX	08/14/2023	
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	ANDA072096	08/14/2023	

Labeler - Melaleuca, Inc (139760102)

Revised: 8/2023

Melaleuca, Inc