

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:
 - 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 a 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

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
- 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, 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

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 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 at 20 weeks or later in 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)
- avoid excessive heat above 40°C (104°F)
- Read all warnings and directions before use
- save carton for complete drug facts information and warnings

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 of comments? call 208-534-3000

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

Drug Facts (continued)
 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, upset stomach, or stomach pain, you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke, or you are taking a diuretic.
 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 stroke, because ibuprofen may decrease this benefit of aspirin, or 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 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.
 Idaho P-486 ID 83402
 To order: 208-534-3000
 Melaleuca.com
 N. 2232 0824 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 at 20 weeks or later in 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.
 Directions do not take more than directed, the smallest effective dose should be used, adults and children 12 years and over 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 20°-25°C (68°-77°F), avoid excessive heat above 40°C (104°F), read 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



CounterAct[®] IB

Ibuprofen Tablets 200 mg

Pain Reliever and Fever Reducer (NSAID)

Nonprescription-Strength Medicine for Body Aches & Pains



50 Coated Tablets

Melaleuca

CounterAct[®] IB

Ibuprofen Tablets 200 mg

Pain Reliever and Fever Reducer (NSAID)

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

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

| Active ingredient (in each tablet) | Purpose |
|--|-----------------------------|
| Ibuprofen 200 mg (NSAID) ¹ | Pain reliever/fever reducer |
| ¹ 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 redness, rash, ulcers. 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. That risk is higher if you use more than directed or for longer than directed.

Mylan

CounterAct[®] IB

Ibuprofen Tablets
200 mg

Pain Reliever and
Fever Reducer (NSAID)

50 Coated Tablets



NOT FOR RESALE

**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 ■ toothache
■ minor pain of arthritis ■ muscular aches ■ the common cold
■ 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. **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. That risk is higher if you use more than directed or for longer than directed. **If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in 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 over: ■ 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 20°–25°C (68°–77°F) ■ avoid excessive heat above 40°C (104°F) ■ read all warnings and directions before use

Questions or comments? call 208-534-3000

DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING

LM1015

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: 8/2024

Melaleuca, Inc