# COUNTERACT IB- ibuprofen tablet, coated Melaleuca, Inc

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### CounterAct IB Content of Label

### **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
- o headache
  - muscular aches
  - o 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:
- o feel faint
  - vomit blood

- have blood ro 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:
- o ask a doctor

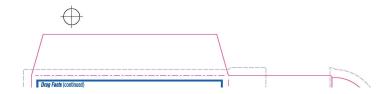
#### Other information

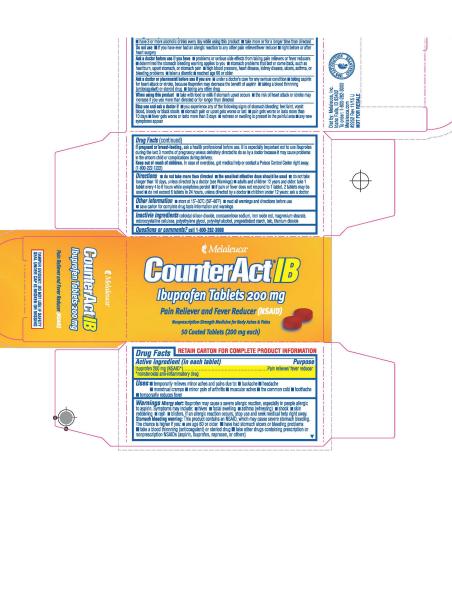
- Store between 20 to 25°C (68 to 77°F)
- Read all warnings and directions before use
- save carton for complete drug facts information and warnings

**Inactive ingredients** collodial silicon dioide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, 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







## **COUNTERACT IB**

ibuprofen tablet, coated

Prod	luct I	Intor	mat	ion

Product Type HUMAN OTC DRUG Item Code (Source) NDC:54473-308

Active	Ingredient/Active	Moiety
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Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE 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				

P	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)

Revised: 1/2023 Melaleuca, Inc