COUNTERACT IB- ibuprofen tablet, film coated
Melaleuca, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CounterAct IB Content of Label

Active ingredient (in each white tablet)
Ibuprofen USP, 200 mg (NSAID)*
*nonsteroidal anti-inflammatory drug

Purpose
Pain reliever/fever reducer

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

Warnings
Allergy alert: Ibuprofen may cause severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
- hives
- facial swelling
- asthma (wheezing)
- skin reddening
- shock
- 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:
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- take more or for a longer time than directed
- have 3 or more alcoholic drinks every day while using this product

Do not use
- right before or after heart surgery
- if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you
- 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 cirrhosis, kidney disease or asthma
- 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
- 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
  - have bloody or black stools
  - vomit blood
  - 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.

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 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 controlled room temperature
- avoid excessive heat 40°C (104°F)

Inactive ingredients cellulose, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, polydextrose, polyethylene glycol, povidone, silica, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

Questions or 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, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54473-134
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white (White)	**Score**	no score
Shape	ROUND (Round)	**Size**	10mm
Flavor		**Imprint Code**	44;352
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-134-50	1 in 1 BOX		
1		50 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/18/2010	

Labeler - Melaleuca, Inc. (139760102)

Revised: 4/2011 Melaleuca, Inc.