IBUPROFEN - ibuprofen tablet, film coated
H.J. Harkins Company, 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.

Rite Aid 44-329

Active ingredient(s)

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Use(s)

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

- 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

- 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 you have

- 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 are taking a diuretic
- you have asthma
- you have problems or serious side effects from taking pain relievers or fever reducers

Ask a doctor or pharmacist before use if you are

- taking any other drug
- 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
- 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,
- children under 12 years: ask a doctor

Other information

- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)
- use by expiration date on package

Inactive ingredients

carnauba wax, corn starch, fumed silica gel, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

Questions?

To Report Adverse Drug Event Call: (800) 616-2471

Principal Display Panel

The product packaging shown below represents a sample of that currently in use. Additional packaging may also be available.

MAJOR®

NDC 0904-7915-80

†Compare to the active ingredient in Advil® Tablets

See New Warnings Information

Ibuprofen

Tablets

Ibuprofen Tablets, USP 200 mg

Pain Reliever

Fever Reducer **(NSAID)**

1000 COATED TABLETS

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

50844 REV0910B29116

Distributed by

MAJOR PHARMACEUTICALS

31778 Enterprise Drive

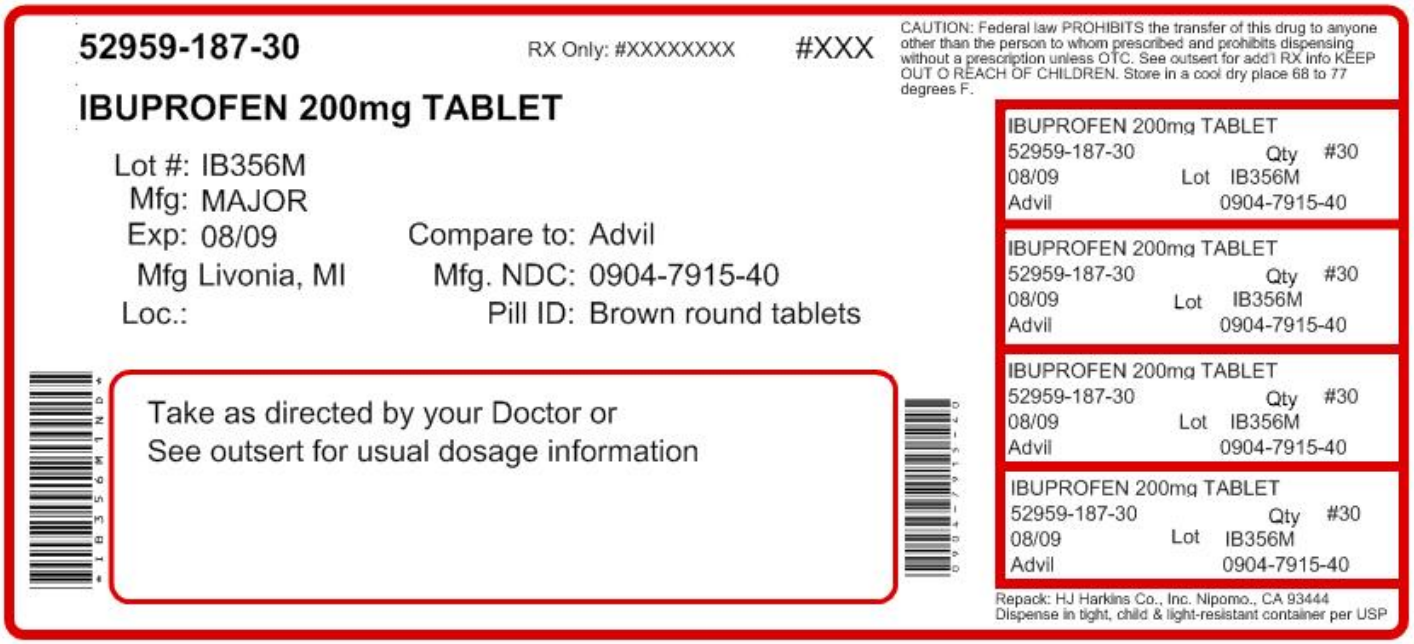
Livonia, MI 48150 USA M-17 Rev.11/10

Re-order No. 700643

Repacked by:

H.J. Harkins Company, Inc.

Nipomo, CA 93444



Product Packaging

IBUPROFEN

ibuprofen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52959-187(NDC:0904-7915)
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**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;291

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-187-00	100 in 1 BOTTLE, PLASTIC		
2	NDC:52959-187-02	120 in 1 BOTTLE, PLASTIC		
3	NDC:52959-187-03	200 in 1 BOTTLE, PLASTIC		
4	NDC:52959-187-10	10 in 1 BOTTLE, PLASTIC		
5	NDC:52959-187-15	15 in 1 BOTTLE, PLASTIC		
6	NDC:52959-187-20	20 in 1 BOTTLE, PLASTIC		
7	NDC:52959-187-21	21 in 1 BOTTLE, PLASTIC		
8	NDC:52959-187-24	24 in 1 BOTTLE, PLASTIC		
9	NDC:52959-187-25	25 in 1 BOTTLE, PLASTIC		
10	NDC:52959-187-30	30 in 1 BOTTLE, PLASTIC		
11	NDC:52959-187-40	40 in 1 BOTTLE, PLASTIC		
12	NDC:52959-187-50	50 in 1 BOTTLE, PLASTIC		
13	NDC:52959-187-60	60 in 1 BOTTLE, PLASTIC		
14	NDC:52959-187-90	90 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	05/24/1988	

Labeler - H.J. Harkins Company, Inc. (147681894)

Registrant - H.J. Harkins Company, Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	repack, relabel

Revised: 2/2012 H.J. Harkins Company, Inc.