# IBUPROFEN- ibuprofen tablet, film coated Meijer Distribution Inc

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Meijer Distribution, Inc. Ibuprofen Tablets, 200 mg Drug Facts

## Active ingredient (in each caplet)

Ibuprofen 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 NSAID, which may cause severe stomach 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

# 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
- have bloody 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 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets in 24 hours, unless directed by a doctor

Children under 12 years: ask a doctor

### Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid high humidity and excessive heat above 40°C (104°F)

# **Inactive ingredients**

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, iron oxides, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, stearic acid, talc, titanium dioxide

## Questions or comments?

1-800-719-9260

## **Principal Display Panel**

Compare to Motrin® IB active ingredient

Easy Open Cap

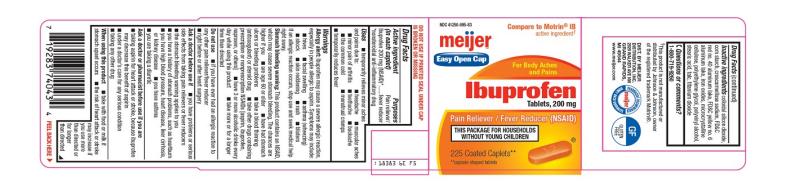
For Body Aches and Pains

Ibuprofen Tablets, 200 mg

Pain Reliever / Fever Reducer (NSAID)

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

\*\*capsule shaped tablets



# **IBUPROFEN**

ibuprofen tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41250-995	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (IBUPRO FEN)	IBUPROFEN	200 mg	

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE			
STARCH, CORN			
CROSCARMELLOSE SODIUM			
CELLULO SE, MICRO CRYSTALLINE			
POLYVINYL ALCOHOL			
STEARIC ACID			
TALC			
TITANIUM DIO XIDE			
POLYETHYLENE GLYCOLS			
FD&C YELLOW NO. 6			
FERRIC O XIDE RED			

Product Characteristics			
Color	ORANGE	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	I2
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-995-83	225 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077349	04/01/1993	

# Labeler - Meijer Distribution Inc (006959555)

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