# IBUPROFEN- ibuprofen capsule, liquid filled The Kroger Co.

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#### **DRUG FACTS**

## Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)\*

(present as the free acid and potassium salt)

\*nonsteroidal anti-inflammatory drug

# Purpose

Pain reliever/ fever reducer

#### Uses

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

## **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

#### 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

- 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
- 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 (1-800-222-1222) 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 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

#### Other information

• each capsule contains: potassium 20 mg

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

# **Inactive ingredients**

FD&C blue #1, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol

#### **Questions or Comments?**

Call toll free 1-800-632-6900

### **Principal Display Panel**

Compare to the active ingredient in Advil® Liqui- Gels® †See bottom panel

## Important: Read all product information before using

**EASY OPEN CAP** 

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Ibuprofen Capsules 200 mg

Pain reliever/ fever reducer (NSAID)

160 CAPSULES\*\*

soft gelatin capsules\*\*

\*\*(Liquid filled capsules)

†Advil® is a registered trademark of pfizer consumer healthcare, Madison, NJ 07940. Pfizer consumer healthcare is not affiliated with the Kroger co. or this product

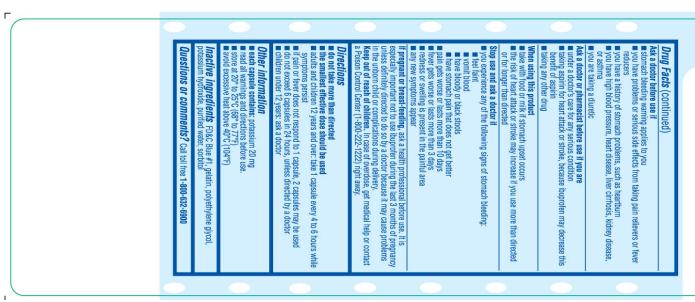
#### DISTRIBUTED BY THE KROGER CO.

## **CINCINNATI, OHIO 45202**

Do not use if seal under cap imprinted with "SEALED FOR YOUR PROTECTION" is broken or missing.

#### **Product Label**





#### Ibuprofen capsules 200 mg

**IBUPROFEN** 

## ibuprofen capsule, liquid filled **Product Information** Product Type HUMAN OTC DRUG LABEL Item Code (Source) NDC:30142-123 Route of Administration ORAL DEA Schedule Active Ingredient/Active Moiety **Basis of Strength Ingredient Name** Strength **IBUPROFEN** IBUPROFEN (IBUPROFEN) 200 mg **Inactive Ingredients**

Ingredient Name	Strength
FD&C BLUE NO. 1	
GELATIN	
POLYETHYLENE GLYCOLS	
PO TASSIUM HYDRO XIDE	
WATER	
SORBITOL	

Product Characteristics					
Color	BLUE	Score	no score		
Shape	CAPSULE	Size	19 mm		
Flavor		Imprint Code	A356		
Contains					

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:30142-123-16	1 in 1 BOX				
1		160 in 1 BOTTLE, PLASTIC				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA202300	07/12/2012			

# Labeler - The Kroger Co. (006999528)

Revised: 9/2012 The Kroger Co.