IBUPROFEN- ibuprofen capsule, liquid filled
Mckesson (Sunmark)

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
- 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 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

- 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 are taking a diuretic

Ask a doctor or pharmacist before use if

- 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 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 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. Keep carton
- store at 20°- 25°C (68°- 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.
- do not use if Tamper Evident seal under bottle cap imprinted with "Sealed for your protection" is broken or missing
- †This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil®

Inactive ingredients

FD&C blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol

Questions or Comments

Call toll free **1-877-753-3935 Monday- Friday 9AM- 5PM EST**

Principal Display Panel

Ibuprofen 200 mg capsules

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:49348-568
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (IBUPROFEN)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1	
GELATIN	
POLYETHYLENE GLYCOLS	
POTASSIUM HYDROXIDE	
WATER	
SORBITAN	
SORBITOL	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	IB200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-568-47	1 in 1 CARTON		
1		20 in 1 BOTTLE		
2	NDC:49348-568-59	1 in 1 CARTON		
2		40 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	07/09/2010	

Labeler - Mckesson (Sunmark) (177667227)

Revised: 10/2012 Mckesson (Sunmark)