## IBUPROFEN- ibuprofen capsule, liquid filled Hy-Vee

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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
  - o 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 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
  - o 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.

## 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
  - o 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° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.

## **Inactive ingredients**

FD&C red #40, FD&C yellow #6, gelatin, mannitol, pharmaceutical ink, polyethylene glycol 600, potassium hydroxide, purified water, sorbitan, sorbitol

## Questions or comments?

Call toll free1-800-289-8343 Monday-Friday 9AM to 4PM CST

## **Principal Display Panel**

## **Ibuprofen Capsules**

Pain Reliever/Fever Reducer (NSAID)

†Compare to the Active Ingredient of Motrin®

Softgels\*\*

(\*\*Liquid filled capsules)

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Motrin®.

DISTRIBUTED BY HY-VEE, INC.

WEST DES MOINES, IA 50266

www.hy-vee.com

CALL 1800-289-8343

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

## **Product Label**

Exp. Date Lot No.:

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PLD-A336A FC002432



DISTRIBUTED BY HY-VEE, INC. WEST DES MOINES, IA 50266 SATISFACTION GUARANTEED CALL 1-800-289-8343 www.hy-vee.com

**Drug Facts** (continued)

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■ the risk of heart attack or stroke may increase if you use more than directed or for longer than directed take with food or milk if stomach upset occurs

# Stop use and ask a doctor

 you experience any of the following signs of stomach bleeding ■ feel faint ■ have bloody or black stools ■ vornit blood

This product is not manufactured or distributed by McNeil Consumer

Healthcare, owner of the registered trademark Motrin<sup>e</sup>

Call toll free 1-800-289-8343 Monday-Friday 9AM-4PM CST

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Hyvee health

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Ibuprofen

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- take a blood thinning (anticoagulant) or steroid drug have had stomach ulcers or bleeding problems
- take other drugs containing prescription or nonprescription NSAIDs ■ have 3 or more alcoholic drinks every day while using this product If you have ever had an allergic reaction to any other pain take more or for a longer time than directed (aspirin, ibuprofen, naproxen, or others) Do not use †COMPARE TO

## the Active Ingredient of Motrin<sup>®</sup>

NDC 42507-408-40



## Capsules

Pain Reliever/Fever Reducer (NSAID)





40 softgels" 200 mg EACH (\*\*LIQUID FILLED CAPSULES)

## **IBUPROFEN**

ibuprofen capsule, liquid filled

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42507-408

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

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Ingredient Name	Basis of Strength	Strength
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg

## **Inactive Ingredients**

inactive ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	

## **Product Characteristics**

SORBITOL (UNII: 506T60A25R)

1 Toutet Characteristics			
Color	ORANGE	Score	no score
Shape	CAPSULE	Size	19 mm
Flavor		Imprint Code	IB200
Contains			

## **Packaging**

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:42507-408- 40	1 in 1 BOX	0 1/3 1/2 0 15	
1	40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	0 1/3 1/2 0 15	

## **Labeler -** Hy-Vee (006925671)

Revised: 12/2019 Hy-Vee