

## **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
  - 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
  - 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**
- 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**

- do not chew, crush, or dissolve capsule before swallowing
- 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.

### **Inactive ingredients**

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

### **Questions or Comments?**

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

### **Principal Display Panel**

†Compare to Advil® Liqui-Gels® active ingredient

Ibuprofen Capsules 200 mg

Pain reliever/ fever reducer (NSAID)

Softgels\*\*

\*\* (Liquid filled capsules)

†This product is not manufactured or distributed by Pfizer consumer healthcare, owner of the registered trademark Advil® Liqui- Gels®

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**  
**DO NOT USE IF TAMPER- EVIDENT SEAL UNDER BOTTLE CAP IMPRINTED WITH**  
**"SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.**

### **Product Label**

**HyVee health** NDC 42507-131-80  
**Ibuprofen Capsules**  
 Pain Reliever/  
 Fever Reducer  
 (NSAID)  
 Actual Size  
**80 SOFTGELS™**  
 200 mg EACH  
 (\*\*LIQUID FILLED CAPSULES)

**†COMPARE TO**  
 the Active Ingredient of  
 Advil® Liqui-Gels®

**Drug Facts (continued under label)**

Lot No.: 7545018340  
 Exp. Date: 07/12/12  
 R1-D-470 LB00292 Rev# 03/12 0  
 DISTRIBUTED BY: HY-VEE, INC.  
 WESTY DES MOINES, IA 50368  
 SANITIZATION GUARANTEED  
 CALL 1-800-288-8343  
 www.hy-vee.com

**Drug Facts**  
**Active ingredient (in each capsule)** Purpose  
 Sustained Ibuprofen (NSAID) 200 mg Pain reliever/fever reducer  
 present as the free acid and potassium salt  
 nonsteroidal anti-inflammatory drug

**Uses**  
 temporarily relieves minor aches and pains due to:  
 ■ headaches ■ 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 redness ■ rash ■ blisters  
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**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  
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 ■ take a blood thinner (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 its benefit or aspirin ■ taking any other drug

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

**Drug Facts (continued)**

**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**  
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 ■ 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  
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**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.  
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**Directions**  
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 ■ take 1 capsule every 4 to 6 hours while symptoms persist  
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 ■ children under 12 years: ask a doctor

**Other information**  
 ■ each capsule contains potassium 20 mg  
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 ■ avoid excessive heat above 40°C (104°F). Protect from light.

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

**Questions or comments?** Call toll free 1-800-288-8343 Monday-Friday 9AM-4PM CST

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**Hy Vee Ibuprofen Capsules**

IBUPROFEN			
ibuprofen capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-131
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
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
GELATIN (UNII: 2G86QN327L)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
SORBITAN (UNII: 6O92ICV9RU)			
Product Characteristics			
Color	BLUE	Score	no score

<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	IB200
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-131-49	1 in 1 BOX	04/13/2013	
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:42507-131-80	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/13/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	04/13/2013	

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

**Registrant** - P & L Development, LLC (079765031)

Revised: 12/2019

Hy-Vee