IBUPROFEN- ibuprofen capsule, liquid filled Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd

Ibuprofen Capsules (Liquid Filled), 200 mg

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
- toothache
- backache
- menstrual cramps
- the common cold
- muscular aches
- minor pain of arthritis
- ♦ 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

Heart attack and stroke warning

NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer 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, asthma, or had a stroke
- 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

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
- you have symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling

- 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

- 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)

Inactive ingredients

FD&C green #3, gelatin, polyethylene glycol, potassium hydroxide, purified water, sorbitol sorbitan solution, and white ink

Questions or commonts?

Call toll free: 1-855-215-8180

PRINCIPAL DISPLAY PANEL

Ibuprofen Capsules mini 200 mg

NDC 53345-059-01

QTY/case: 12,000 capsules

Caution: for further manufacturing, processing or repackaging.

Humanwell PuraCap Pharmaceuticals (Wuhan) Co.,Ltd

NDC #: 53345-059-01

Customer Item: BK000921



IBUPROFEN 200MG MINI SG Walmart

LOT # XXXXXXX

MFG DATE:YYYY/ MM/DD



QTY/Case: 12,000 capsules

CAUTION:

PO#:

FOR FUTURE MANUFACTURING, PROCESSING OR REPACKAGING IMPORTANT:

1.Protect from heat, humidity, and light.

2.Store at 20-25°C (68-77F) and avoid excessive heat above 40℃ (104F) .

Made in China

COMMENTS:

REV-00

2025/08

001

IBUPROFEN

ibuprofen capsule, liquid filled

_	 	
Drad	Inform	2tion
		a

HUMAN OTC DRUG NDC:53345-059 **Product Type Item Code (Source)**

Route of Administration ORAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name Strength

POTASSIUM HYDROXIDE (UNII: WZ H3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN TYPE B BOVINE (150 BLOOM) (UNII: F5AJW0ONK4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics				
Color	green (clear)	Score	no score	
Shape	OVAL	Size	6mm	
Flavor		Imprint Code	P33	
Contains				

	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NDC:53345-059- 01	1 in 1 CARTON	12/28/2025			
	1	12000 in 1 BAG; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA206568	12/28/2025		

Labeler - Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd (421293287)

Establishment				
Name	Address	ID/FEI	Business Operations	
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(53345-059)	

Revised: 12/2025 Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd