

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

Ibuprofen Capsules 200 mg

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
- blister

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take 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 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)

Inactive ingredients

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

Questions or comments

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL - Shipper Label

Ibuprofen Capsules 200mg, 20ct

Quantity: 35 Bottles

NDC No.:53345-014-02

MADE IN CHINA

IMPORTANT:

1. Inspect immediately upon receipt.
2. This is a bulk shipment, intended for further processing only.
3. Protect from heat, humidity, and light. Do not refrigerate.
4. Store at 20-25°C (68-77)°F

Humanwell Puracap Pharmaceuticals (Wuhan)Co., Ltd

No. 99, 2nd Shendun Road, East Lake New Technology Development District,
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-014-02

Product:

Ibuprofen Capsules 200mg, 20ct

Each softgel contains: Ibuprofen 200 mg,

Each bottle contains: 20 capsules,

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

41-10019

Quantity:

35 Bottles

Lot Number:

XXXXXXX

Manufacturing Date:

mm/yyyy

Box No.:

IMPORTANT:

1. Inspect immediately upon receipt.
2. This is a bulk shipment, intended for further processing only.
3. Protect from heat, humidity, and light. Do not refrigerate.
4. Store at 20-25°C (68-77°F)

MADE IN CHINA

REV-01

04/2017

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53345-014

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	green (Clear)	Score	no score
Shape	CAPSULE (Oblong)	Size	18mm
Flavor		Imprint Code	PC16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-014-02	35 in 1 BOX	07/13/2017	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206568	07/13/2017	

Labeler - Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd (421293287)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(53345-014) , analysis(53345-014)