

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

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, 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

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.
- 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 ink

Questions or comments

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

PRINCIPAL DISPLAY PANEL - Shipper Label

Ibuprofen Capsules 200 mg

Quantity: 10,000 Capsules

NDC No.:53345-014-01

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.: 53345-014-01

Product:

Ibuprofen Capsules 200 mg

Each softgel contains: Ibuprofen 200 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00011

Quantity:

10000 Capsules

Lot Number:

xxxxxxx

Manufacturing Date:

xx/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-00

08/2016

Humanwell PuraCap Pharmaceuticals (Wuhan) Co.,Ltd

NDC #: 53345-014-01

PLD Item: BK000435



BK000435

IBUPROFEN 200MG GREEN SOFTGEL BULK

LOT # XXXXXXX

MFG DATE: DD/MM/YY



XXXXXXXX



DD/MM/YY

QTY/Case: 10,000 capsules



CAUTION: FOR FUTURE MANUFACTURING, PROCESSING OR REPACKAGING	IMPORTANT: 1. Protect from heat, humidity, and light. 2. Store at 20-25°C (68-77°F) and avoid excessive heat above 40°C (104°F) .
Made in China	

COMMENTS:
PO#:

REV-01
03/2018

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: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	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: 059QF0KO0R)	

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:53345-014-01	1 in 1 BOX	10/06/2016	
1		10000 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	10/06/2016	

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)

Revised: 11/2019

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd