IBUPROFEN- ibuprofen capsule, liquid filled PuraCap Pharmaceutical LLC

Ibuprofen Capsules (Liquid Filled), 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
 - o 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 conditon
- 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

gelatin, medium-chain triglycerides, 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, 200 mg

Pain Reliever/Fever Reducer (NSAID)

80 Liquid Filled Capsules

NDC 51013-410-26



READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts

Active ingredient (in each capsule) Solubilized ibuprofen equal to

200 mg ibuprofen (NSAID)**

Purpose

Symptoms may include: ■ facial swelling ■ asthma (wheezing)

Drug Facts (continued)

■ 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.

Uses

temporarily relieves minor aches and pains due to:

(present as the free acid and potassium salt)

*nonsteroidal anti-inflammatory drug

- headache
- toothache
- backache the common cold

Pain reliever/Fever reducer

- menstrual cramps 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.

Drug Facts (continued)

- 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

Drug Facts (continued)

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.



NDC 51013-410-26



buprofen

Ibuprofen Capsules, 200 mg

Liquid Filled Softgels

Pain Reliever/Fever Reducer (NSAID)





READ AND KEEP CARTON FOR COMP WARNINGS AND INFORMATION

imprinted with

common the Do Not Use if seal under bottle cap imprinte "SEALED for YOUR PROTECTION" is broken or

π temporarily relieves minor aches and pains due to headache, toothache, backache, menstrual cramps, headache, toothache, backache, menstrual or cold, muscular aches, minor pain of arthritis. reduces temporarily

use if you are pregnant, under a doctor's care age 60 or over, taking any other drug or have cause a severe allergic reaction, especially Warnings Ask your doctor before use if for a serious condition, age 6 This product may stomach problems.

people allergic to as prim. Symptoms may include: hives, factal everillm, as threat (wheezing), shock, skin reddening, rash, blisters swelling, asthma (wheezing), shock, if an allergic reaction occurs, stop

right away.

Do not use this productif you have ever had an alleigic reaction to any pair re-is-verfever reducer.

Stormach bleeding warming: This product contains a nonsteroidal

anti-inflammatory drug (NSA D), which may cause severe storrach bleeding. The chance is higher if you

• take a blood thinning (anticoagulant) or steroid drug • take other drugs containing prescription or nonprescription NSALDs [aspirin, ibuprofen, naproxen, or others] are age 60 or ofder
 have had stomach ulcers or bleeding problems

[aspirin, ibuprofen, naproxen, or 3 or more alcoholic drinks

every day while

more or for a longer time than directed

Drug Facts (continued under

www.discount-drugmart.com DISTRIBUTED BY DRUG MART-FOOD

Lot No.:

MEDINA, OHIO 44256 Made in China



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.

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 capsub, 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 Each capsule contains: potassium 20 mg

Questions or comments? call toll free: 1-855-215-8180

SATISFACTION GUARANTEED IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGE TO STORE WHERE PURCHASED. IF UNA BLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPTY PACKAGE TO: DISCOUNT DRUG MART, 211 COMMERCE DRIVE, MEDINA, OHO 44:256

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:510 13-410

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthIBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)IBUPRO FEN200 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

POTASSIUM HYDRO XIDE (UNII: WZH3C48 M4T)

SORBITAN (UNII: 6O92ICV9RU) SORBITOL (UNII: 506T60A25R)

WATER (UNII: 059QF0KO0R)

Product Characteristics

Color	yellow (Clear Natural)	Score	no score
Shape	CAPSULE (Oblong)	Size	18 mm
Flavor		Imprint Code	P24
Contains			

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:51013-410-26	1 in 1 CARTON	07/14/2017				
1	80 in 1 BOTTLE; Type 0: Not a Combination Product					
Marketing Information						
Marketing Category	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA206568	07/14/2017				

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment				
Name	Address	ID/FEI	Business Operations	
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-410), analysis(51013-410)	

Revised: 12/2019 PuraCap Pharmaceutical LLC