

IBUPROFEN- ibuprofen capsule, liquid filled
CHAIN DRUG MARKETING ASSOCIATION INC.

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 at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause delivery 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° to 25°C (68° to 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 **1-888-235-2466**

DO NOT USE IF TAMPER-EVIDENT SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED for YOUR PROTECTION" IS BROKEN OR MISSING.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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Questions: 800-935-2362

R0522

L0000620

20's Carton

Quality Choice

NDC 63868-427-20

†Compare to the Active Ingredient in Advil® LIQUI-GELS®

Ibuprofen

Ibuprofen Capsules, 200 mg

mini capsule

Liquid Filled Softgels

Pain Reliever/Fever Reducer (NSAID)


Smaller Capsule

Same Strength

20 Softgels**

**Liquid Filled Capsules

NDC 63968-427-20



Ibuprofen

Ibuprofen Capsules, 200 mg
Liquid Filled Softgels

Pain Reliever/Fever Reducer (NSAID)
Smaller Capsule • Same Strength

Compare to the Active Ingredient in Advil® LIQUID-GELS™

20 Softgels™ **200 mg**

Actual Size

Drug Facts (continued)

■ **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, avoid aspirin, because 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

■ **aspirin** or **other heart surgery**

Ask a doctor before you use it ■ **somewhat 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 disease, 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 the benefit of aspirin ■ **taking any other drug**

When using this product ■ **take with food or milk if somewhat upset** occurs

Drug Facts

Active ingredient (in each capsule) _____ **Purpose**
Sulbuzidol (ibuprofen) equal to 200 mg Ibuprofen (NSAID) * _____ 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: ■ 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 (breathing) ■ shock ■ skin redness ■ rash ■ blister, if 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)

Drug Facts (continued)

Other information ■ read all warnings and directions before use. Keep carbon ■ store at 20° to 25°C (68° to 77°F) ■ avoid excessive heat above 40°C (104°F). Fritted 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 1-888-235-2466

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IBUPROFEN
ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-427
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)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	IB4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-427-20	1 in 1 CARTON	07/16/2020	
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	ANDA078682	07/16/2020	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC. (011920774)**Registrant** - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(63868-427)

Revised: 12/2022

CHAIN DRUG MARKETING ASSOCIATION INC.