

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

For India Manufacturing Site:

FD&C Blue #1, gelatin, 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

†All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Advil® LIQUI-GELS®.

Distributed by C.D.M.A., Inc. ©

Novi, MI 48375

www.qualitychoice.com

Questions: 800-935-2362

R1024

L0000921

For India Manufacturing Site:

MADE IN INDIA

Code: TN/DRUGS/TN/25/00074

P2455/00/25

R0325 L0001017

20's Carton

QC

QUALITY

CHOICE

NDC 83324-203-20

†Compare to the

Active Ingredient in

Advil® LIQUI-GELS®

Ibuprofen

Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer

(NSAID)

20 Softgels**

****Liquid Filled Capsules**

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
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NDC 83324-203-20

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

Ibuprofen

Ibuprofen Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID)



20 Softgels** **Liquid Filled Capsules

Actual Size

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Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362



Item # 99613



6 355151 99613 7

Lot No.:

Exp. Date:

DO NOT USE IF TAMPER-EVIDENT SEAL UNDER CAPSULE IS BROKEN OR MISSING. KEEP OUT OF REACH OF CHILDREN. SEE BACK OF BOX FOR COMPLETE WARNINGS AND INFORMATION.

Questions or comments?
call toll-free 1-888-235-2466

Inactive ingredients: FD&C Blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan and sorbitol

Drug Facts (continued)

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.

Drug Facts

Active ingredient (in each capsule) Solubilized 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 (wheezing) ■ shock ■ skin reddening ■ rash ■ blisters. If an allergic reaction occurs, stop use and seek medical help right away.
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L0000921 R1024

Drug Facts (continued)

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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

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

20's carton-Made In India label

QC

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CHOICE

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Capsules, 200 mg

Pain Reliever/Fever Reducer (NSAID)

20 Softgels**

****Liquid Filled Capsules**

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R0325 L0001017
MADE IN INDIA
Code: TN / DRUGS / TN/25/00074
P455/0025
Distributed by CDMA, Inc.
www.challiboychoice.com
Questions: 800-935-2362
SAFETY ACTION GUARANTEE
item # 99613
6 35515 99613 7
UNZ
27 mm x 14 mm
(Width x Height)
Lot No.:
Exp. Date:

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Ibuprofen
Capsules, 200 mg
Pain Reliever/Fever Reducer (NSAID)
20 Softgels** **Liquid Filled Capsules Actual Size

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IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83324-203 |
| 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 | 20mm |
| Flavor | | Imprint Code | IB1 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:83324-203-20 | 1 in 1 CARTON | 08/11/2025 | |
| 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 | 08/11/2025 | |

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC. (011920774)

Registrant - Bionpharma Inc. (079637826)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|----------------|---------------|----------------------------|
| Patheon Softgels Inc. | | 002193829 | manufacture(83324-203) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|----------------|---------------|----------------------------|
| ESJAY PHARMA PRIVATE LIMITED | | 957309497 | manufacture(83324-203) |

Revised: 9/2025

CHAIN DRUG MARKETING ASSOCIATION INC.