

PAIN RELIEF- ibuprofen capsule, liquid filled
Bionpharma 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**

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

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

†All trademarks are property of their respective owners. This product is not affiliated

with the owners of Advil® LIQUI-GELS®.

Manufactured for:

BIONPHARMA

Princeton, NJ 08540

R0223

L0000705

For India Manufacturing Site:

Manufactured for:

Bionpharma Inc.

Princeton, NJ 08540

MADE IN INDIA

Code: TN/DRUGS/TN/25/00074

R0125

L0000939

P3238/01/24

300's count label

†**compare to** the active ingredient in **Advil® Liqui-Gels®**

NDC 69452-260-

a+health

pain relief

ibuprofen capsules,

200 mg (NSAID)

pain reliever/fever reducer

300softgels**

****liquid filled capsules**

† compare to the active ingredient
in Advil® LIQUI-GELS®

NDC 69452-260-83

a+health™

pain relief
ibuprofen capsules,
200 mg (NSAID)

300 softgels**

**pain reliever/
fever reducer**

**liquid-filled capsules

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 - the common cold ■ muscular aches ■ minor pain of arthritis
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- skin reddening
- rash
- blisters

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- 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

Manufactured for:
Bionpharma Inc.
Princeton, NJ 08540



Lot No.: L0000705
R0223

Exp. date: 8



T00129R0422

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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

Other information

- each capsule contains **potassium 20 mg**
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- store at 20° to 25° C (68° to 77° F)
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Directions

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300's count label-Made In India

† compare to the active ingredient in **Advil® Liqui-Gels®**

NDC 69452-260-83

a+health

pain relief

ibuprofen capsules,

200 mg

pain reliever/fever reducer

(NSAID)

300 softgels**

**liquid filled capsules

(MADE IN INDIA)

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in Advil® LIQUI-GELS®

NDC 69452-260-83

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pain relief
ibuprofen capsules,
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*nonsteroidal anti-inflammatory drug

Purpose

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

L0000939
 Manufactured for:
Bionpharma Inc.
 Princeton, NJ 08540



MADE IN INDIA
 Code: TN/DRUGS/TN25/0074
 Lot No. P2328/0124
 Exp. Date:

PEEL
HERE

Non Varnish Area

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

Inactive ingredients
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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

■ **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 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.

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
 ■ 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

Drug Facts (continued)

PAIN RELIEF

ibuprofen capsule, liquid filled

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69452-260 |
| 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) | |

T00129R0125

| | |
|------------------------------------------------------------|--|
| 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 | IB200 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:69452-260-11 | 1 in 1 CARTON | 05/01/2019 | |
| 1 | | 20 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:69452-260-78 | 1 in 1 CARTON | 05/01/2019 | |
| 2 | | 80 in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:69452-260-79 | 160 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2019 | |
| 4 | NDC:69452-260-82 | 240 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2019 | |
| 5 | NDC:69452-260-83 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 05/01/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|------------------------------------------|----------------------|--------------------|
| ANDA | ANDA078682 | 05/01/2019 | |

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|------------------------|
| Patheon Softgels Inc. | | 002193829 | manufacture(69452-260) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

Revised: 3/2025

Bionpharma Inc.