# DYE-FREE PAIN RELIEF- ibuprofen capsule, liquid filled Bionpharma Inc.

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# **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

 $\blacksquare$  facial swelling  $\blacksquare$  asthma (wheezing)  $\blacksquare$  shock  $\blacksquare$  skin reddening  $\blacksquare$  rash  $\blacksquare$  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
- $\blacksquare$  you have a history of stomach problems, such as heartburn  $\blacksquare$  you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke  $\blacksquare$  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 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° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.

## Inactive ingredients

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.

†This product is not manufactured or distributed by the owners of Advil® LIQUI-GELS®.

Manufactured for: **Bionpharma Inc.** 

Princeton, NJ 08540

#### MADE IN INDIA

Code: TN / DRUGS / TN/25/00074

P3466/00/25

L0001104 R0725

#### 400s label

**†Compare to** the active ingredient in

Advil® Liqui-Gels® minis

a+health™

dye-free

pain relief

Ibuprofen capsules,

200 mg

pain reliever/

fever reducer

(NSAID)

400 capsules\*\*

\*\*liquid-filled capsules

mini

### capsule



■ read all warnings and directions before use
■ store at 20° to 25°C (68° to 77°F)
■ avoid excessive heat above 40°C (104°F). Protect from light ■ you have symptoms of heart problems or stroke:

a chest pain ■ trouble breathing ■ weakness in one part or side of body ■ sturred 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 ■ under a doctor's care for any serious condition ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this you have a history of stomach problems, such as heartburn stomach bleeding warning applies to y or serious side effects from taking pain r 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 ■ the smallest do not take more than directed cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or ■ you experience any of the following signs of stomach bleeding:
■ feel faint
■ reel faint
■ vomit blood
■ have bloody or black stools Drug Facts (continued) each capsule contains: potassium 20 mg the smallest effective dose should be used
 adults and children 12 years and over: take 1 capsule every 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 Stop use and ask a doctor if When using this product take with food or milk if stomach upset occurs Ask a doctor or pharmacist before use if you are Ask a doctor before use if kidney disease, asthma, or had a stroke ■ you are taking a diu This product is not manufactured or distributed by the owners of Adville LIQUI-GELS® penefit of aspirin ■ taking any other drug have stomach pain that does not get better under 12 years: ask a doctor unless definitely directed to do so by a doctor because it may ene glycol, potassium hydroxide, purified water, g applies to you ■you have problems taking pain relievers or fever reducers call toll-free 1-888-235-2466 heart disease, liver cirrhosis

# **DYE-FREE PAIN RELIEF**

ibuprofen capsule, liquid filled

T00307R0725

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-513
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

GELATIN, UNSPECIFIED (UNII: 2G86QN327L)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

WATER (UNII: 059QF0KO0R)

POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)

SORBITAN (UNII: 6O92ICV9RU)

SORBITOL (UNII: 506T60A25R)

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	IB5
Contains			

Packaging			
# Item Code Package Description		Marketing Start Date	Marketing End Date
1 NDC:69452-513	400 in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	10/27/2025	

# Labeler - Bionpharma Inc. (079637826)

# Registrant - Bionpharma Inc. (079637826)

Establishment			
Name	Address	ID/FEI	Business Operations
ESJAY PHARMA PRIVATE LIMITED		957309497	pack(69452-513) , manufacture(69452-513)

Revised: 10/2025 Bionpharma Inc.