# PAIN RELIEF- ibuprofen capsule, liquid filled Albertsons Companies

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#### Ibuprofen Capsules, 200 mg -mini capsule

#### 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 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 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

**READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION** (8's Bottle Label/Carton)

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

**DISTRIBUTED BY:**BETTER LIVING BRANDS LLC

P.O. BOX 99, PLEASANTON, CA 94566-0009

1-888-723-3929

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L0000692

RD 23096

#### 80's Bottle Carton

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

NDC 21130-220-78

mini

capsule

Pain Relief

**IBUPROFEN** 

CAPSULES, 200 mg

Pain Reliever/Fever Reducer

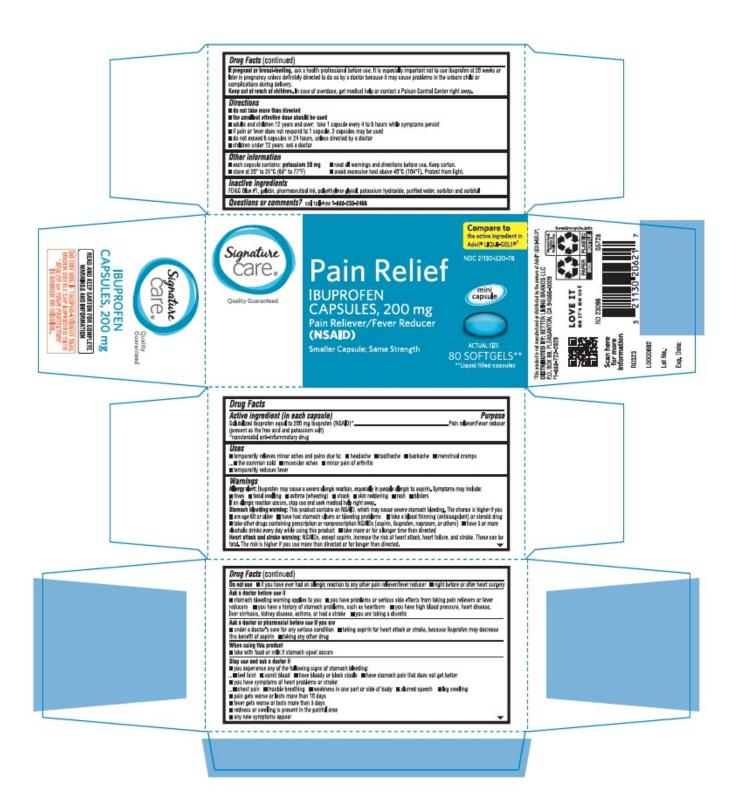
(NSAID)

**Smaller Capsule, Same Strength** 

80 Softgels\*\*

\*\*Liquid filled capsules

†This product is not affiliated with the owners of Advil  $^{\rm @}$  LIQUI-GELS  $^{\rm @}$  .



#### **PAIN RELIEF**

ibuprofen capsule, liquid filled

| OTC DRUG  | H CI- (C)          |               |
|-----------|--------------------|---------------|
| JIC DINOG | Item Code (Source) | NDC:21130-220 |
|           |                    |               |
|           |                    |               |
|           |                    |               |

| 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 600 (UNII: NL4J9F21N9) |          |  |  |  |
| POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)     |          |  |  |  |
| WATER (UNII: 059QF0KO0R)                   |          |  |  |  |
| SORBITAN (UNII: 6092ICV9RU)                |          |  |  |  |
| SORBITOL (UNII: 506T60A25R)                |          |  |  |  |

| Product Characteristics |         |              |          |
|-------------------------|---------|--------------|----------|
| Color                   | blue    | Score        | no score |
| Shape                   | CAPSULE | Size         | 15mm     |
| Flavor                  |         | Imprint Code | IB4      |
| Contains                |         |              |          |

| ı | Packaging            |   |                         |                       |  |
|---|----------------------|---|-------------------------|-----------------------|--|
| 4 | # Item Code          | Package Description                                   | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:21130-220-<br>78 | 1 in 1 CARTON   | 09/26/2023              |                       |  |
| 1 | L                    | 80 in 1 BOTTLE; Type 1: Convenience Kit of Co-Package |                         |                       |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA                  | ANDA078682                                  | 09/26/2023              |                       |
|                       |   |                         |                       |

# Labeler - Albertsons Companies (009137209)

# Registrant - Bionpharma Inc. (079637826)

| Establishment         |         |           |                            |  |
|-----------------------|---------|-----------|----------------------------|--|
| Name                  | Address | ID/FEI    | <b>Business Operations</b> |  |
| Patheon Softgels Inc. |         | 002193829 | manufacture(21130-220)     |  |

Revised: 9/2023 Albertsons Companies