# IBUPROFEN PM- ibuprofen, diphenhydramine hcl capsule, liquid filled KROGER COMPANY

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### Ibuprofen PM capsules

### Active ingredients

### (in each capsule)

Diphenhydramine hydrochloride 25 mg

Solubilized ibuprofen equal to

200 mg ibuprofen (NSAID) \*

(present as the free acid and potassium salt)

### **Purposes**

Nighttime sleep-aid

Pain reliever

#### Uses

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep

### 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

<sup>\*</sup>nonsteroidal anti-inflammatory drug

- 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
- unless you have time for a full night's sleep
- in children under 12 years of age
- right before or after heart surgery
- with any other product containing diphenhydramine, even one used on skin
- if you have sleeplessness without pain

#### 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
- you have a breathing problem such as emphysema or chronic bronchitis
- you have glaucoma
- you have trouble urinating due to an enlarged prostate gland

### Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers, or any other sleep-aid
- under a doctor's care for any continuing medical illness
- taking any other antihistamines
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin

■ taking any other drug

### When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive a motor vehicle or operate machinery
- 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
- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness
- 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
- adults and children 12 years and over: take 2 capsules at bedtime
- do not take more than 2 capsules in 24 hours

#### 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, FD&C red #40, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

#### **Questions?**

call toll-free 1-800-632-6900

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF

PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

\*\*\*Advil ® PM LIQUI-GELS ® is a registered trademark of Haleon US Holdings LLC,

Liquid-Gels is a registered trademark oof Catalent Pharma Solutions, Inc.

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

**OUR PHARMACIST RECOMMENDED** 

**OUR BRANDS OUR GUARANTEE** 

LOVE IT OR YOUR MONEY BACK.

WWW.KROGER.COM

FOR MORE PRODUCT INFORMATION, SCAN UPC USING YOUR KROGER APP OR CALL 800-632-6900

L0000834

R0424

Lot No .:

Exp. Date:

### 40's count carton label

COMPARE TO the active ingredients of Advil® PM LIQUI-GELS®

Kroger®

health

Ibuprofen PM

Ibuprofen & Diphenhydramine HCl

Solubilized Ibuprofen, 200 mg/ Diphenhydramine HCl, 25 mg

Pain Reliever (NSAID)/ Nighttime Sleep-Aid

actual size

40 SOFTGEL\*\*

**CAPSULES** 

\*\*liquid filled capsules



#### **IBUPROFEN PM**

ibuprofen, diphenhydramine hcl capsule, liquid filled

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:30142-232

Route of Administration ORAL

| Active Ingredient/Active Moiety   |                                  |          |  |
|---|----------------------------------|----------|--|
| Ingredient Name   | Basis of Strength                | Strength |  |
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)                                  | IBUPROFEN                        | 200 mg   |  |
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE<br>HYDROCHLORIDE | 25 mg    |  |

| Inactive Ingredients                                |          |
|---|----------|
| Ingredient Name                                     | Strength |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                  |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                  |          |
| 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 (BLUE) | Score        | no score |
| Shape                   | OVAL (OVAL) | Size         | 19mm     |
| Flavor                  |             | Imprint Code | IBPM1    |
| Contains                |             |              |          |

| Packaging |                      |  |                         |                       |
|-----------|----------------------|--|-------------------------|-----------------------|
| #         | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:30142-<br>232-15 | 1 in 1 CARTON  | 08/24/2021              |                       |
| 1         |                      | 40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |
| 2         | NDC:30142-<br>232-78 | 1 in 1 CARTON  | 08/24/2021              |                       |
| 2         |                      | 80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |                         |                       |

| Marketing Information                                       |            |                         |                       |
|---|------------|-------------------------|-----------------------|
| Marketing Application Number or Monograph Category Citation |            | Marketing Start<br>Date | Marketing End<br>Date |
| ANDA  | ANDA090397 | 08/24/2021              |                       |

## Labeler - KROGER COMPANY (006999528)

# Registrant - Bionpharma Inc. (079637826)

| Establishment         |         |           |                            |  |
|-----------------------|---------|-----------|----------------------------|--|
| Name                  | Address | ID/FEI    | <b>Business Operations</b> |  |
| Patheon Softgels Inc. |         | 002193829 | manufacture(30142-232)     |  |

Revised: 12/2025 KROGER COMPANY