PAIN RELIEF PM- ibuprofen, diphenhydramine hcl capsule, liquid filled
Bionpharma Inc.

Drug Facts

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)

*nonsteroidal anti-inflammatory drug

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

■ 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.

■ 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 or comments?

Call toll free **1-888-235-2466**

Manufactured for:

Bionpharma

Princeton, NJ 08540

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

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Principal Display Panel

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

NDC 69452-264-22

a+health

pain relief pm

solubilized ibuprofen, 200 mg/

diphenhydramine HCl, 25 mg

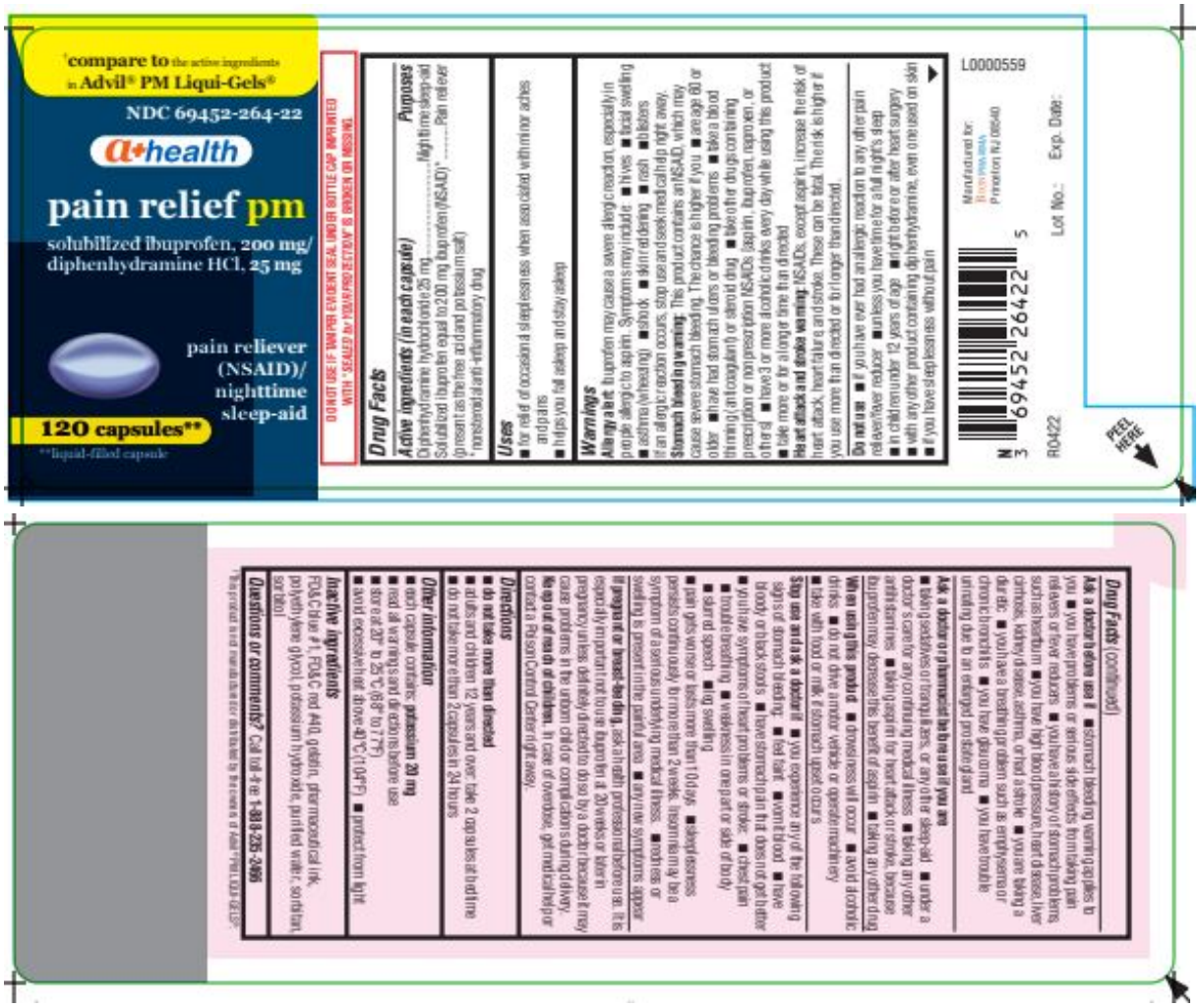
pain reliever (NSAID)/

nighttime

sleep-aid

120 capsules**

**liquid-filled capsule



PAIN RELIEF PM

ibuprofen, diphenhydramine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69452-264
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE 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: 3WQ0SDW1A)	

POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	IBUPM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-264-22	120 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	ANDA090397	05/01/2019	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Patheon Softgels Inc.		002193829	manufacture(69452-264)

Revised: 12/2022 Bionpharma Inc.