

**HEMORRHOIDAL- mineral oil, petrolatum, phenylephrine hcl ointment
Bionpharma Inc.**

hemorrhoidal, A+ Health

Active ingredient

Mineral Oil 14%

Petrolatum 74.9%

Phenylephrine HCl 0.25%

Purpose

Protectant

Protectant

Vasoconstrictor

Uses

- Helps relieve the local itching and discomfort associated with hemorrhoids
- Temporarily shrinks hemorrhoidal tissue and relieves burning
- Temporarily provides a coating for relief of anorectal discomforts
- Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings

For external and/or intrarectal use only

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you

are presently taking a prescription drug for high blood pressure or depression.

When using this product

do not exceed the recommended daily dosage unless directed by a doctor.

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days ■ bleeding occurs
- introduction of applicator into the rectum causes additional pain

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ **Adults:** When practical, cleanse the affected area by patting or blotting with an appropriate cleansing pad. Gently dry by patting or blotting with toilet tissue or a soft cloth before applying ointment.

■ Apply to affected areas up to 4 times daily.

■ EXTERNAL USE: Apply to affected area

■ FOR INTRARECTAL USE: ■ Remove cover from the applicator ■ Attach applicator to tube ■ Lubricate applicator well, then gently insert applicator into the rectum ■ Thoroughly clean applicator after each use and replace cover

■ **Children under 12 years of age:** consult a doctor

Other information

■ Store at 15°C – 30°C (59°F – 86°F)

■ Lot No. & Expiry Date: See box or crimp of tube

Inactive ingredients

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thyme oil, vitamin E, white wax

READ AND KEEP CARTON FOR COMPLETE INFORMATION

*This product is not manufactured or distributed by the owners of Preparation H® Hemorrhoidal Ointment.

Manufactured for: **Bionpharma Inc.**, Princeton, NJ 08540

GUJ/DRUGS/G/25/2134

MADE IN INDIA

L0000812

R0424

LOT & EXP.

tube carton

***compare to** the active ingredient in **Preparation H[®] Hemorrhoid Treatment Ointment**

NDC 69452-448-38

a+ health[™]

hemorrhoidal ointment

• **reduces irritation** • **with applicator**

dye-free • **phthalate-free** • **fragrance-free**

- **relieves both internal and external hemorrhoid symptoms**
- **temporarily shrinks swollen hemorrhoidal tissue**
- **prompt, soothing relief from painful burning, itching and discomfort**

net wt. 2 oz



HEMORRHOIDAL

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69452-448
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE	2.5 mg

UNII:1WS297W6MV)	FRONTLEPTORINE	in 1 g
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHITE WAX (UNII: 7G1J5DA97F)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CORN OIL (UNII: 8470G57WFM)	
LANOLIN (UNII: 7EV65EAW6H)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
THYME OIL (UNII: 2UK410MY6B)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-448-38	1 in 1 CARTON	04/10/2025	
1		56 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	04/10/2025	

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		650970176	manufacture(69452-448)

Revised: 3/2025

Bionpharma Inc.