

**ITCH RELIEF- diphenhydramine hydrochloride and zinc acetate cream
Bionpharma Inc.**

diphenhydramine HCl 2 % + zinc acetate 0.1%, A+ Health

Active ingredient

Diphenhydramine Hydrochloride 2%

Zinc Acetate 0.1%

Purpose

Topical Analgesic

Skin Protectant

Uses

- dries the oozing and weeping of poison ivy, poison oak, and poison sumac
- temporarily relieves pain and itching associated with:
 - minor cuts ■ sunburn ■ scrapes
 - minor skin irritations ■ minor burns ■ insect bites
- rashes due to poison ivy, poison oak and poison sumac

Warnings

For external use only.

Do not use

- with any other product containing diphenhydramine, even one taken by mouth
- on large areas of the body
- on broken, blistered, or oozing skin

Ask a doctor before use

- on measles ■ on chicken pox ■ on poison ivy ■ on sunburn

When using this product

avoid contact with the eyes.

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days

■ symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

Directions

- children under 2 years of age: ask a doctor
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- do not use more than directed

Other information

- Store at 15° to 30°C (59° to 86°F) ■ Close the cap tightly after use
- Lot No. & Exp. Date: See box or crimp of tube

Inactive ingredients

carbomer homopolymer type c, cetyl alcohol, glycerin, glyceryl monostearate, light mineral oil, methylparaben, polysorbate 60, propylparaben, purified water, stearic acid

READ AND KEEP CARTON FOR COMPLETE INFORMATION

*This product is not manufactured or distributed by the owners of Benadryl® Extra Strength ItchStopping Cream.

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

MADE IN INDIA

GUJ/DRUGS/G/25/2134

L0000814

R0424

LOT & EXP.

tube carton

* **compare to** the active ingredient in **Benadryl® Extra Strength Itch Stopping Cream**

NDC 69452-449-37

a+ health™

itch relief cream

diphenhydramine HCl 2 % + zinc acetate 0.1%

net wt. 1.25 oz

dye-free • phthalate-free • fragrance-free

- extra strength
- topical analgesic
- skin protectant



ITCH RELIEF

diphenhydramine hydrochloride and zinc acetate cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69452-449 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|-----------------|
| ZINC ACETATE (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37) | ZINC ACETATE | 1 mg in 1 g |
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 20 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| WATER (UNII: 059QF0K00R) | |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:69452-449-37 | 1 in 1 CARTON | 07/16/2024 | |
| 1 | | 35.4 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 | M017 | 07/16/2024 | |

Labeler - Bionpharma Inc. (079637826)

Registrant - Bionpharma Inc. (079637826)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|----------------|---------------|----------------------------|
|-------------|----------------|---------------|----------------------------|

Galentic Pharma (India) Private Limited

650970176

manufacture(69452-449)

Revised: 7/2024

Bionpharma Inc.