

**ALLERGY RELIEF- diphenhydramine hcl capsule, liquid filled  
BIONPHARMA INC.**

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**Diphenhydramine HCl 50mg, A+ Health, allergy relief**

***Active ingredient (in each capsule)***

Diphenhydramine HCl 50 mg

***Purpose***

Antihistamine

***Uses***

- temporarily relieves these symptoms due to hay fever or the other upper respiratory allergies:
- runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes

***Warnings***

- May cause excitability especially in children.
- May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect.

***Do not use***

- for children under 12 years of age ■ with any other product containing diphenhydramine, even one used on skin.

***Ask a doctor before use if you have***

- glaucoma ■ difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis

***Ask a doctor or pharmacist before use***

if you are taking sedatives or tranquilizers.

***When using this product***

- avoid alcoholic beverages ■ be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

sleeplessness persists continuously for more than 2 weeks

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Centre right away.

**Directions**

|                                       |   |
|---------------------------------------|---|
| adults and children 12 years and over | ■ take 1 capsule every 4 to 6 hours, or as directed by a doctor<br>■ do not take more than 6 capsules in 24 hours |
| children under 12 years               | do not use  |

**Other information**

■ store at 20°C to 25°C (68°F to 77°F) ■ avoid high humidity and excessive heat above 40°C (104°F).

■ protect from light

**Inactive ingredients**

gelatin, glycerin, polyethylene glycol 400, polyethylene glycol 600, propylene glycol, purified water, sorbitol sorbitan solution

**Questions or comments?**

call toll-free 1-888-235-2466 (Mon - Fri 9AM - 5PM EST)

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

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

†This product is not manufactured or distributed by the owners of Benadryl® Allergy Extra Strength.

Manufactured for:

**Bionpharma**

Princeton, NJ 08540

Mfg. Lic. No.: TN00002123

L0000864

R0524

2122631

**100's count**

†**Compare to** the active ingredient in **Benadryl® Allergy Extra Strength**

**NDC 69452-452-20**

**a+ health™**

**dye-free**

**extra strength**

**allergy relief**

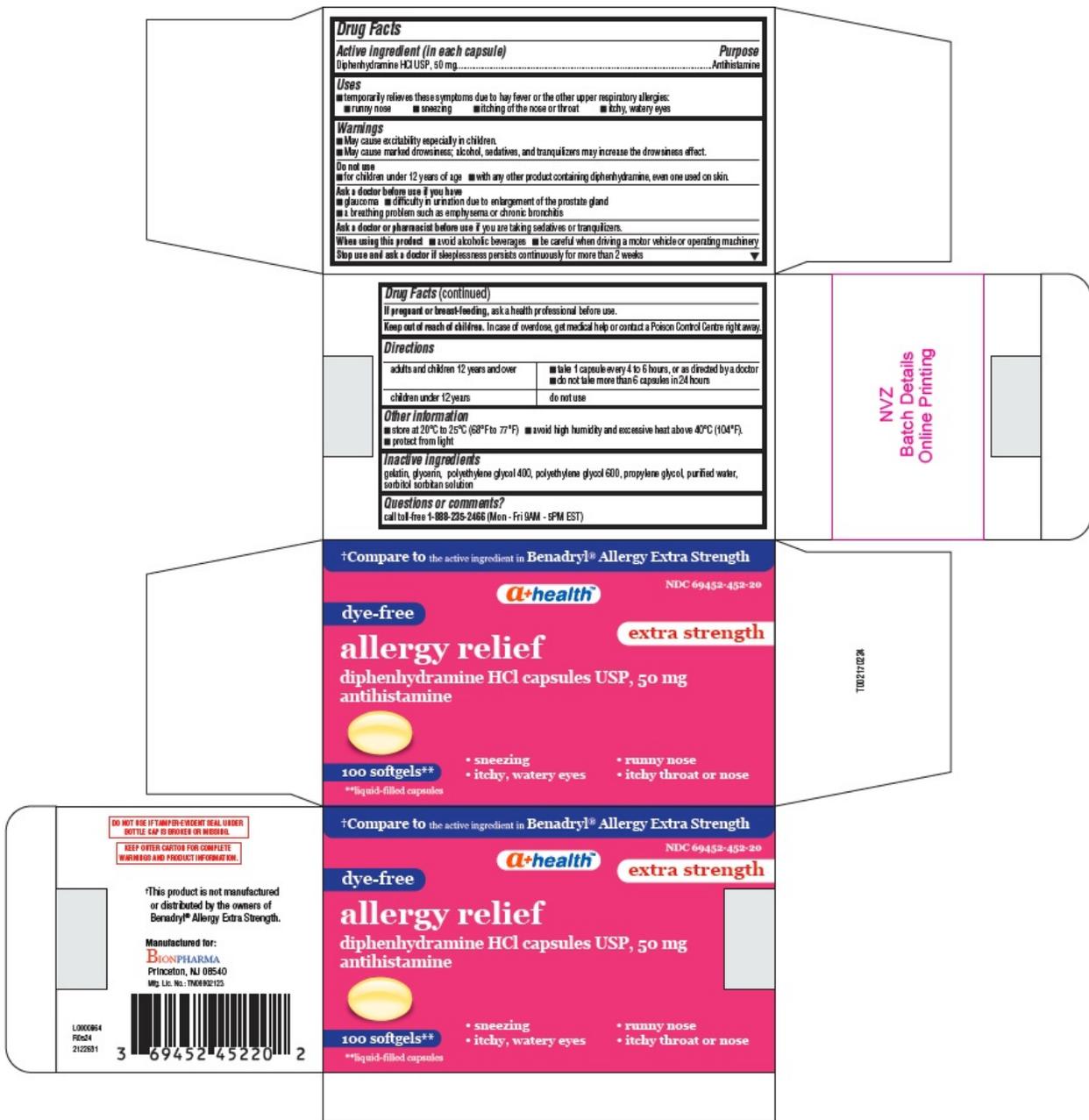
**diphenhydramine HCl capsules USP, 50 mg**

**antihistamine**

- **sneezing • runny nose**
- **itchy, watery eyes • itchy throat or nose**

**100 softgels\*\***

\*\*liquid-filled capsules



## ALLERGY RELIEF

diphenhydramine hcl capsule, liquid filled

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69452-452 |
| <b>Route of Administration</b> | ORAL           |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength                | Strength |
|--|----------------------------------|----------|
| <b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40)<br>(DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE<br>HYDROCHLORIDE | 50 mg    |

## Inactive Ingredients

| Ingredient Name                                   | Strength |
|---|----------|
| <b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9) |          |
| <b>SORBITAN</b> (UNII: 6O92ICV9RU)                |          |
| <b>GELATIN</b> (UNII: 2G86QN327L)                 |          |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ) |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                   |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)        |          |
| <b>SORBITOL</b> (UNII: 506T60A25R)                |          |

## Product Characteristics

|                 |                           |                     |          |
|-----------------|---------------------------|---------------------|----------|
| <b>Color</b>    | white (Clear Transparent) | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL                      | <b>Size</b>         | 13mm     |
| <b>Flavor</b>   |                           | <b>Imprint Code</b> | DF50     |
| <b>Contains</b> |                           |                     |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69452-452-20 | 1 in 1 CARTON                                      | 10/01/2024           |                    |
| 1 |                  | 100 in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:69452-452-83 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 03/02/2026           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 10/01/2024           |                    |

**Labeler** - BIONPHARMA INC. (079637826)

**Registrant** - Bionpharma Inc. (079637826)

## Establishment

| Name                               | Address | ID/FEI    | Business Operations    |
|------------------------------------|---------|-----------|------------------------|
| SOFTGEL HEALTHCARE PRIVATE LIMITED |         | 676666501 | manufacture(69452-452) |