

**BANOPHEN- diphenhydramine hcl capsule**  
**Bryant Ranch Prepack**

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**0836-Major(100C/1000C)**

**Active Ingredient (in each banded capsule)**

Diphenhydramine Hydrochloride 50 mg

**Purpose**

Antihistamine

**Use**

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies

- runny nose
- sneezing
- itchy, watery eyes
- itchy throat and nose
- Temporarily relieves these symptoms due to the common cold
  - runny nose
  - sneezing

**Do not use**

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

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- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

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

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

**Ask a doctor or pharmacist**

before use if you are taking sedatives or tranquilizers

**When using this product**

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

- excitability may occur, especially in children

### **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 Center right away.

### **Directions**

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours

|  |   |
|--|---|
| adults and children 12 years of age and over | Take 1 capsule (50 mg)  |
| children under 12 years of age               | ask a doctor, the proper dosage strength is not available in this package** |

\*\*Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

### **Other Information**

- Store in a dry place at 15° – 30°C (59° – 86°F).
- Do not use if either capsule band or imprinted safety seal under cap is broken or missing
- Protect from moisture
- Contains lactose

### **Inactive Ingredients**

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

### **Questions?**

Questions or comments? 1-800-231-4670

Distributed by: MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

(800) 616-2471

[www.majorpharmaceuticals.com](http://www.majorpharmaceuticals.com)

### **HOW SUPPLIED**

BANOPHEN

## Diphenhydramine Hydrochloride 50mg Capsules

- NDC 63629-9451-1: 30 CAPSULEs in a BOTTLE
- NDC 63629-9451-2: 60 CAPSULEs in a BOTTLE

Store in a dry place at 15° – 30°C (59° – 86°F).



Do not use if either capsule band or imprinted safety seal under cap is broken or missing.

Protect from moisture. Contains lactose.

Repackaged/Relabeled by:  
Bryant Ranch Prepack  
Burbank, CA 91504

## BANOPHEN

## Diphenhydramine Hydrochloride 50mg Capsules

|   |  |
|---|--|
| <br>GTIN 00363629945115<br>Lot 208620<br>Exp 4/22/2028<br>SN 0123456789<br><br>Package Insert | <b>Drug Facts</b><br><b>Active ingredient (in each banded capsule)</b> Diphenhydramine Hydrochloride 50 mg<br><b>Purpose</b> Antihistamine   |
|   | <b>Uses</b><br>Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: •runny nose •sneezing •itchy, watery eyes •itchy throat and nose •Temporarily relieves these symptoms due to the common cold •runny nose •sneezing.  |
|   | <b>Warnings</b><br>Do not use •to make a child sleepy •with any other product containing diphenhydramine, even one used on skin. Ask a doctor before use if you have •glaucoma •a breathing problem such as emphysema or chronic bronchitis •trouble urinating due to an enlarged prostate gland. Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers. When using this product •marked drowsiness may occur •avoid alcoholic drinks •alcohol, sedatives, and tranquilizers may increase drowsiness •be careful when driving a motor vehicle or operating machinery •excitability may occur, especially in children. 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 Center right away. |
|   | <b>Other Information</b><br>•Store at room temperature, USP. •Do not use if either capsule band or imprinted safety seal under cap is broken or missing. •Protect from moisture. •Contains lactose. Scan Package Insert QR Code for more information.  |
|   | <b>Directions</b><br>•Take every 4-6 hours. •Do not take more than 6 doses in 24 hours adults and children 12 years of age and over; Take 1 capsule (50 mg) children under 12 years of age;ask a doctor, the proper dosage strength is not available in this package. Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.  |
| <b>Inactive Ingredients</b><br>D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.  |  |

**NDC 63629-9451-1**

**Banophen Capsules, USP**

**50 mg**

**30 Capsules**



Repackaged by: Bryant Ranch Prepack, Inc. Major Pharmaceuticals  
Burbank, CA 91504 USA

Manufactured by:



## BANOPHEN

diphenhydramine hcl capsule

### Product Information

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:63629-9451(NDC:0904-5307) |
| <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>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH) |          |

|  |  |
|--|--|
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)  |  |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)  |  |
| <b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L) |  |
| <b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)  |  |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)         |  |

### Product Characteristics

|                 |         |                     |          |
|-----------------|---------|---------------------|----------|
| <b>Color</b>    | pink    | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE | <b>Size</b>         | 14mm     |
| <b>Flavor</b>   |         | <b>Imprint Code</b> | CPC;836  |
| <b>Contains</b> |         |                     |          |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63629-9451-1 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 09/26/2022           |                    |
| 2 | NDC:63629-9451-2 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 09/26/2022           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 11/02/2009           | 01/31/2028         |

**Labeler** - Bryant Ranch Prepack (171714327)

**Registrant** - Bryant Ranch Prepack (171714327)

### Establishment

| Name                 | Address | ID/FEI    | Business Operations                      |
|----------------------|---------|-----------|--|
| Bryant Ranch Prepack |         | 171714327 | REPACK(63629-9451) , RELABEL(63629-9451) |

Revised: 4/2026

Bryant Ranch Prepack