

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine
hydrochloride capsule
Proficient Rx LP**

Diphenhydramine Hydrochloride Capsules

Active ingredient

Diphenhydramine Hydrochloride 25 mg

Purpose

Antihistamine

Use

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold, sneezing, runny nose, itchy, watery eyes, itchy throat and nose.

Warnings: 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

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

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

Pregnancy/breast-feeding warning

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years and over: take 25 to 50 mg (1 to 2 capsule) every 4 to 6 hours, not more than 12 capsules in 24 hours.

Children 6 years to 12 years of age: take 12.5 mg** (1 capsule) every 4 to 6 hours, not more than 6 capsules in 24 hours.

Children under 6 years of age: do not use

**12.5mg dosage strength is not available in this package. Do not attempt to break capsule

Other information

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature]. Protect from excessive moisture.

Inactive ingredients

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

Questions?

Questions or comments? (800) 616-2471

Distributed by

MAJOR® PHARMACEUTICALS

31778 Enterprise Drive

Livonia, MI 48150 USA

Repackaged by:

Proficient Rx LP

Thousand Oaks, CA 91320

Re-Order No. 301574

PRINCIPAL DISPLAY PANEL DIPHENHYDRAMINE HCL CAPSULES 25MG



Scan Here



NDC 63187-771-20

Packaged By: Proficient Rx LP
Thousand Oaks, CA 91320

3
631877120
1

Banophen 25mg

#20 Capsules

Each capsule contains: Diphenhydramine HCl 25 mg
Antihistamine

Pink, white capsules with orange band; with imprint "CPC 835" on the capsule

Product ID: PB077120

Dist. By: MAJOR PHARMACEUTICALS 17177 N. Laurel Park Drive, Suite 233, Livonia, MI 48152

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Banophen 25mg
#20 Capsules
Lot #00000 SN# MASTER
NDC 63187-771-20 Exp:00/00/00

Banophen 25mg
#20 Capsules
Lot #00000 SN# MASTER
NDC 63187-771-20 Exp:00/00/00

Banophen 25mg
#20 Capsules
Lot #00000 SN# MASTER
NDC 63187-771-20 Exp:00/00/00



GTIN: 00363187771201
SN# MASTER
Exp. 00/00/00
Lot #:00000

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63187-771(NDC:0904-5306) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|----------|
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| D&C RED NO. 28 (UNII: 767IP0Y5NH) | |

Product Characteristics

| | | | |
|--------------|------|--------------|----------|
| Color | PINK | Score | no score |
|--------------|------|--------------|----------|

| | | | |
|-----------------|---------|---------------------|---------|
| Shape | CAPSULE | Size | 14mm |
| Flavor | | Imprint Code | CPC;835 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:63187-771-20 | 20 in 1 BOTTLE; Type 0: Not a Combination Product | 08/01/2017 | |
| 2 | NDC:63187-771-30 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2016 | |
| 3 | NDC:63187-771-60 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2016 | |
| 4 | NDC:63187-771-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2016 | |

Marketing Information

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

Labeler - Proficient Rx LP (079196022)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|---------------------|
| Proficient Rx LP | | 079196022 | REPACK(63187-771) |

Revised: 1/2024

Proficient Rx LP