

ALLERGY RELIEF- diphenhydramine hydrochloride tablet, coated
FSA STORE INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

1090-CRM-2023-0111

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

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

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

- 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 (1-800-222-1222).

Directions

- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

| | |
|---------------------------------------|----------------|
| adults and children 12 years and over | 1 to 2 tablets |
| children 6 to under 12 years | 1 tablet |
| children under 6 years | do not use |

Other information

- **each tablet contains:** calcium 45 mg
- store between 20-25°C (68-77°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #27 aluminum lake, dibasic calcium phosphate, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

caring mill™

NDC 81522-109-03

†Compare to the active ingredient of Benadryl® Allergy Tablets

Diphenhydramine HCl 25 mg

Antihistamine

- Sneezing • Itchy watery eyes
- Runny Nose • Itchy throat

Actual Size

100 TABLETS



ALLERGY RELIEF

diphenhydramine hydrochloride tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:81522-109

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 |
|--|----------|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| D&C RED NO. 27 (UNII: 2LRS185U6K) | |
| CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| ALUMINUM OXIDE (UNII: LMI26O6933) | |

Product Characteristics

| | | | |
|----------|------|--------------|----------|
| Color | pink | Score | no score |
| Shape | OVAL | Size | 11mm |
| Flavor | | Imprint Code | 25;052 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:81522-109-03 | 1 in 1 CARTON | 01/11/2023 | |
| 1 | | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 01/11/2023 | |

Labeler - FSA STORE INC. (049283340)

