ALLERGY RELIEF- diphenhydramine hydrochloride tablet, coated Shield Pharmaceuticals Corp

Allergy Relief

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
- itchy, watery eyes
- sneezing
- 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

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

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 (1-800-222-1222) right away.

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 25 mg
- store between 20-25° C (68-77° F)
- protect from moisture and light

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate, FD&C red no. 3, hypromellose, magnesium stearate, microcrystalline cellulose, phloxine B lake*, polyethylene glycol, polyvinyl alcohol, stearic acid*, talc, titanium dioxide

Questions or comments?

1-800-373-6981

Distributed by: **Shield Pharmaceuticals Corp.** Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL

Allergy Relief
Diphenhydramine HCl 25 mg
Label

^{*}may contain this ingredient



croscarmellose sodium, dha sic calcium phosphate, FD&C red no. 3, hypromellose, magnesium stearate, microcrystalline cellulose, phloxine B lake*, poyethylene glycol, polyvinyl alcohol, stearing acid*, talç, thamium dioxide Consumer Inc. McNeil Consumer Healthcare, owner of the registered trademark Benadry® Allengy. 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). 1 to 2 tablets **if pregnant or breast-feeding**, ask a health professional This product is not manufactured or distributed by Johnson & Johnson do not use 1 tablet *Inactive ingredients* colloidal silicon dioxide Questions or comments? 1-800-373-6981 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 ■ each tablet contains: calcium 25 mg ■ store between 20-25° C (68-77° F) ■ protect from moisture and light children 6 to under 12 years Oruq Facts (continued 'may contain this ingredien children under 6 years Other information Directions

ALLERGY RELIEF

diphenhydramine hydrochloride tablet, coated

| Product Information | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:83059-0117 |
| 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 | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | |
| PHLOXINE (UNII: QDW0T759T6) | | |
| POLYVINYL ALCOHOL (UNII: 532B59J990) | | |

| STEARIC ACID (UNII: 4ELV7Z65AP) | |
|--|--|
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C RED NO. 3 (UNII: PN2ZH5LOQY) | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | |

| Product Characteristics | | | |
|-------------------------|---------|--------------|----------|
| Color | pink | Score | no score |
| Shape | CAPSULE | Size | 11mm |
| Flavor | | Imprint Code | S4 |
| Contains | | | |

| l | Packaging | | | | | |
|---|-----------|----------------------|--|-------------------------|-----------------------|--|
| | # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| | 1 | NDC:83059- 0117-3 | 300 in 1 BOTTLE; Type 0: Not a Combination Product | 12/04/2027 | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 12/04/2025 | |
| | | | |

Labeler - Shield Pharmaceuticals Corp (118724924)

Revised: 12/2025 Shield Pharmaceuticals Corp