GOOD SENSE ALLERGY RELIEF- diphenhydramine hydrochloride capsule L. Perrigo Company

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.

Perrigo Allergy Relief Drug Facts

Active ingredient (in each capsule)

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

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

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

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 doses in 24 hours

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

Other information

- store at 20-25°C (68-77°F). Avoid high humidity. Protect from light.
- each capsule is sealed with a Uni Band® seal which bonds the two capsule halves together. Do not use if seal is broken or missing. Do not use if blister unit is broken or torn.

Inactive ingredients

anhydrous lactose, benzyl alcohol, butylparaben, D&C red no. 28, edetate calcium disodium, edible ink, FD&C blue no. 1, FD&C red no. 40, gelatin, magnesium stearate, methylparaben, polysorbate 80, propylparaben, sodium lauryl sulfate, sodium propionate

Questions or comments?

1-800-719-9260

Principal Display Panel

Easy to Swallow

Allergy Relief Capsules

Diphenhydramine HCI 25 mg – Antihistamine

Actual Size

Sneezing

Itchy, Watery Eyes

Runny Nose

Itchy Throat

Compare to active ingredient of Benadryl® Allergy

24 Capsules



OPEN OTHER END

Important: Read all product information before using. Keep this box for important information.

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Purpose

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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 diphenhy dramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as emphy sema or chronic bronchitis ■ glaucoma
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Drug Facts (continued)

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Questions or comments? 1-800-719-9260

Glute n Free



GOOD SENSE ALLERGY RELIEF

diphenhydramine hydrochloride capsule

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0113-0462

ORAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE - DIPHENHYDRAMINE UNII:8GTS82S83M)

HYDROCHLORIDE

25 mg

CONVENIENT RECLOSING TAB

Distributed By Perrigo®Allegan, MI 49010

Inactive Ingradients

| mactive ingredients | |
|---|----------|
| Ingredient Name | Strength |
| ANHYDRO US LACTO SE (UNII: 3SY5LH9 PMK) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| BUTYLPARABEN (UNII: 3QPI1U3FV8) | |
| D&C RED NO. 28 (UNII: 767IP0 Y5NH) | |

| EDETATE CALCIUM DISO DIUM (UNII: 25IH6 R4SGF) | |
|---|--|
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9 127XOA) | |
| GELATIN (UNII: 2G86QN327L) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| METHYLPARABEN (UNII: A2I8 C7HI9 T) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| PROPYLPARABEN (UNII: Z8 IX2SC1OH) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| SODIUM PROPIONATE (UNII: DK6 Y9 P42IN) | |

| Product Characteristics | | | |
|-------------------------|---|--------------|----------|
| Color | PINK (clear), WHITE (clear), RED (band) | Score | no score |
| Shape | CAPSULE | Size | 14mm |
| Flavor | | Imprint Code | L462 |
| Contains | | | |

| l | Packaging | | | |
|---|--------------------|--|-----------------------------|---------------------------|
| l | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 NDC:0113-0462-62 | 24 in 1 CARTON | 09/15/1989 | |
| l | 1 | 1 in 1 BLISTER PACK; 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 | 09/15/1989 | |
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Labeler - L. Perrigo Company (006013346)

Revised: 1/2017 L. Perrigo Company