ALLERGY RELIEF- diphenhydramine hydrochloride tablet Health Pharma USA LLC

Allergy Relief - Diphenhydramine Hydrochloride 25 mg

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - o Runny nose
 - o Sneezing
 - o Itchy, watery eyes
 - o Itchy nose or throat
- Temporarily relieves these symptoms of the common cold:
 - o Runny nose
 - o 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

- Trouble urinating due to an enlarged prostate gland
- Glaucoma
- A breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if youaretaking sedatives or tranquilizers

When using this product

- Marked drowsiness may occur
- Avoid alcoholic drinks
- Excitability may occur, especially in children
- Alcohol, sedatives and tranquilizers may increase drowsiness
- Be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding,

ask a health professional before use

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Take every 4 to 6 hours, or as directed by a doctor

Do not take not more than 6 doses in 24 hours

- Adults and children 12 years and over:1 or 2 caplets
- Children 6 to under 12 years :1 caplet
- Children under 6 years: do not use

Other Information

- Each caplet contains: Calcium 23.52 mg
- Store between 20-25°C (68-77°F)
- Protct from light

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive Ingredients

May Contains:

Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Colloidal Silicon Dioxide, Magnesium Stearate, film coaat AMB pink, Polyethylene Glycol, Polyvinyl Alcohol, Phloxine B lake, Titanium dioxide, Talc

Questions or comments?

Call 1-844-832-1138

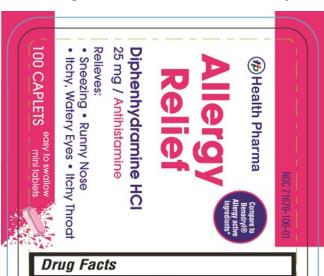
9 AM- 4 PM Monday - Friday

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Diphenhydramine Hydrochloride 25 mg/Antihistamine

Compare to Benadryl ® Allergy active ingredients*

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner



Active ingredient (in each caplet)

Purpose

Diphenhydramine HCl 25mg.....Antihistamine

Uses:

- Temporarily relieves these symptoms due to hav fever or other upper respiratory allergies:
- Runny nose Sneezing Itchy, watery eyes
- Itchy nose or throat
- Temporarily relieves these symptoms of 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

- Trouble urinating due to an enlarged prostate gland
- Glaucoma
- A breathing problem such as emphysema or chronic

Ask your doctor or pharmacist before use if you are taking sedative or tranquilizers.

When using this product

- Marked drowsiness may occur
- Avoid alcoholic drinks
- Excitability may occur, especially in children
- Alcohol, sedatives and tranquilizers may increase drowsiness
- Be careful when driving a motor vehicle or operating

DRUG FACTS CONTINUED on back of the label

TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Benadryl® Allergy.

Mfg / Dist by: Health Pharma Rahway, NJ 07065





Lot No .:

HERE

Exp. Date:



Drug Facts (Continued)

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

Keep out of reach of children.

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Directions

Take every 4 to 6 hours, or as directed by a doctor Do not take more than 6 doses in 24 hours

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- Children under 6 years: do not use

Other information

- Each caplet contains: Calcium 23.52 mg
- Store between 20-25°C (68-77°F)
- Protect from light.

Inactive ingredients: May Contains:

dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, stearic acid, colloidal silicon dioxide, magnesium stearate, film coat AMB pink, polyethylene glycol, polyvinyl alcohol, phloxine B lake, titanium dioxide, talc

Questions or comments? Call 1-844-832-1138 9 AM - 4 PM Monday - Friday

ALLERGY RELIEF

diphenhydramine hydrochloride tablet

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71679-106 |
|-------------------------|----------------|--------------------|---------------|
| 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 | |
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | | |
| D&C RED NO. 28 (UNII: 767IP0Y5NH) | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | |
| TALC (UNII: 7SEV7J4R1U) | | |

| Product Characteristics | | | |
|-------------------------|---------|--------------|----------|
| Color | pink | Score | no score |
| Shape | CAPSULE | Size | 11mm |
| Flavor | | Imprint Code | D25 |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:71679-106- 01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 05/12/2012 | |
| 2 | NDC:71679-106- 06 | 600 in 1 BOTTLE; Type 0: Not a Combination Product | 05/12/2012 | |
| 3 | NDC:71679-106- 10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 05/12/2012 | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M012 | 05/12/2012 | |
| | | | |

Labeler - Health Pharma USA LLC (080804485)

| Establishment | | | | |
|-----------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Health Pharma USA LLC | | 080804485 | manufacture(71679-106) | |

Revised: 10/2023 Health Pharma USA LLC