

ALLERGY RELIEF- diphenhydramine hydrochloride tablet
NEWVUE LLC

DIPHENHYDRAMINE HCl Tablets, USP 25mg

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
- 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 bronchitis

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
- 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, contact a doctor or Poison Control Center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do not exceed recommended dosage.

Directions

- **take every 4 to 6 hours, not more than 6 doses in 24 hours**
- **Adults and children 12 years of age and older:**1 or 2 tablets
- **children 6 to under 12 years of age:**1 tablet
- **children 4 to under 6 years of age:**do not use unless directed by a doctor
- **children under 4 years of age:**do not use

Other Information

- each tablet contains : calcium 20 mg
- store at controlled room temperature 20°-25°C (68°-77°F).
- read all product information before using.
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive Ingredients

Colloidal silicon Dioxide, Croscarmellose Sodium, Dicalcium Phosphate, D & C Red, Magnesium stearate, Microcrystalline cellulose, Polyvinyl alcohol, Titanium dioxide, Talc

Questions or Comments

www.getnewvue.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

DIPHENHYDRAMINE HYDROCHLORIDE TABLET

, USP 25 MG

ANTIHISTAMINE

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

83813-002-01 1000 Caplets

ALLERGY RELIEF

Diphenhydramine HCl • 25 mg

ANTIHISTAMINE

RELIEF OF:

- Sneezing & Runny Nose • Itchy, Watery Eyes
- Hay Fever Symptoms
- Itching of Nose or Throat

1000 TABLETS / 25 MG EACH

EASY TO SWALLOW TABLETS

Drug Facts

Active ingredient (in each caplet) **Purpose**

Diphenhydramine HCl 25 mg Antihistamine

Use

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- itchy, watery eyes
- sneezing
- itchy nose or throat
- temporarily relieves these symptoms of the 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
- trouble urinating due to an enlarged prostate gland

Ask your doctor or pharmacist before use if you are

- a breathing problem such as emphysema or chronic bronchitis
- taking the blood thinning drug warfarin

Ask your doctor or pharmacist before use if you are

- taking sedatives or tranquilizers

Drug Facts (continued)

When using this product

- drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution 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. Overdose warning:** In case of an 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

- protect from moisture
- store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)

Drug Facts (continued)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, d&c red 27, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, titanium dioxide, talc

Questions? www.GetNewVue.com

Distributed By: NewVue LLC
Greenville, SC 29607
www.GetNewVue.com
Made in U.S.A.
GLUTEN FREE

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DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED.

ALLERGY RELIEF

diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83813-002
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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	11mm
Flavor		Imprint Code	N;02

Contains

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83813-002-01	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2012	



SEE CARTON FOR COMPLETE DRUG FACTS Drug Facts

Purpose Active ingredient (in each caplet)

Diphenhydramine HCl 25mg.....Antihistamine

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

When using this product

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Directions

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 - do not take more than 6 doses in 24 hours
- Adults and children 12 years and over: 1 or 2 caplets
children 6 to under 12 years of age: 1 caplet
children under 6 years of age: do not use
- DO NOT USE IF IMPRINTED SAFETY SEAL
UNDER CAP IS BROKEN OR MISSING

Distributed by: Safrel Pharmaceuticals LLC, Bridgewater, NJ 08807
www.safrelpharma.com

Lot No.:

Exp. Date:

Marketing Information

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

Labeler - NEWVUE LLC (119120572)

Revised: 4/2024

NEWVUE LLC