

ALLERGY RELIEF- diphenhydramine hcl 25 mg tablet
Pioneer Life Sciences, LLC

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.

Diphenhydramine HCl 25 mg

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

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
- 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 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

- if needed, repeat dose every 4 to 6 hours
- do not take more than 6 times in 24 hours
- adults and children 12 years of age or older - 1 to 2 caplets
- children 6 to under 12 years - 1 caplet
- children under 6 years of age - do not use.

Other information

each tablets contains:

calcium 15 mg

store between 20-25°C (68-77°F). Avoid high humidity

Inactive ingredients

dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, OPADRY II

Questions or comments?

Call 1-732-698-5070 Monday through Friday 9AM–5PM EST or www.pioneerlifesciences.com

Distributed by:

Pioneer Life Sciences
40E Cotters Lane, Suite A
East Brunswick, NJ 08816

†compare to **BENADRYL®** active ingredients.



Allergy Relief

antihistamine

DIPHENHYDRAMINE HCl
25mg each tablet

250 caplets
not actual size

NDC 72090-021-25

Drug Facts

Active Ingredient (in each caplet)	Purpose
Diphenhydramine HCl 25mg	Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 ■ runny nose ■ sneezing
 ■ itchy, watery eyes ■ 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
 ■ 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 taking sedatives or tranquilizers

When using this product
 ■ marked drowsiness may occur
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Drug Facts (continued)

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
 ■ if needed, repeat dose every 4 to 6 hours
 ■ do not take more than 6 times in 24 hours

age	daily dosage
adults and children 12 years of age or older	1 to 2 caplets
children 6 to under 12 years	1 caplet
children under 6 years of age	do not use this product children under 6 years of age

Other information
 each tablet contains: ■ calcium 15 mg
 ■ store between 20-25°C (68-77°F). Avoid high humidity.

inactive ingredients
 dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, opadry II

Drug Facts (continued)

Questions or comments?
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†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark BENADRYL® Tablets.



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TAMPER EVIDENT Do not use if safety seal under cap is broken or missing.

Lot No.
Exp. Date

ALLERGY RELIEF

diphenhydramine hcl 25 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72090-021
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)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-021-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2018	

