

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.

Active Ingredient

Diphenhydramine Hcl 25mg

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 Doctor:

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 DOCTOR/PHARMACIST:

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

PREGNANCY

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

KEEP OUT OF REACH OF CHILDREN

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 24 mg - store between 20-25°C (68-77°F). Avoid high humidity. Protect from moisture and light

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

PRINCIPAL DISPLAY PANEL

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

GenCare
generic healthcare

Allergy Relief
antihistamine

DIPHENHYDRAMINE HCl
25mg each tablet

For the temporary relief of:

- Sneezing • Itchy throat
- Runny nose
- Itchy, watery eyes

1000 tablets
not actual size; actual shape may vary

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
■ 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

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. ■ Protect from moisture and light

Inactive ingredients
colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, D&C red #27 Al lake, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide.

Drug Facts (continued)

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

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

6 80044 64869 9

Distributed by: Pioneer Life Sciences
40E Cutters Ln Suite A, East Brunswick, NJ 08816

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	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)				
Product Characteristics				
Color	pink	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	S4	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-021-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	06/29/2020		

Labeler - Pioneer Life Sciences, LLC (014092742)