ALLERGY RELIEF- diphenhydramine hydrochloride tablet
HealthLife of USA

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 25mg, USP

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 youare 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

1-844-832-1138 (Mon-Fri 9AM-5PM EST) or www.healthlifeofusa.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.**

69517-106-24 24 Caplets

ALLERGY RELIEF

diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69517-106
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE 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**	EL
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69517-106-24	24 in 1 BOTTLE	01/01/2016	
1		1 in 1 CARTON; Type 0: Not a Combination Product		
2	NDC:69517-106-30	1 in 1 CARTON	06/05/2017	
2		30 in 1 BOTTLE; 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	05/12/2012	

Labeler - HealthLife of USA (079656178)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd.		915664486	manufacture(69517-106)