DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet Simpex Pharma Pvt. Ltd

Diphenhydramine hydrochloride

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine hydrochloride 25 mg

Purpose

Antihistamine

Uses

temporarily relieves symptoms due to common cold, hay fever or other allergies affecting the upper respiratory tract

- runny nose
- sneezing
- Itchy watery eyes
- Itching of the nose or throat.

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin.

Consult your doctor if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland.

Consult your doctor if you are taking sedatives or tranquilizers

- sedative, 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 or reach of children.

In case of overdose, get medical help or contact a poison control center right away.

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks.

Directions:

- take every 4 to 6 hours
- do not take more than 6 does in 24 hours
- Adult and children 12 years of age and over 1 to 2 tablet
- Children 6 to 12 years of age 1 tablet
- Children 6 years of age do not use this product in children under 6 years

Other Information

- each tablet contains: Calcium 25 mg/tablet
- store at room temperature 15°-30° (59°-86° F)
- protect from light and moisture

Inactive ingredient

carnauba wax, colloidal anhydrous silica, croscarmellose sodium, dibasic calcium phosphate, hydroxy propyl methyl cellulose phthalate HP-55, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, polysorbate 80, polyvinyl alcohol, talc, titanium dioxide, xanthan gum,

Package Labeling:



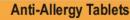


Antihistamine DIPHENHYDRAMINE HYDROCHLORIDE

100 Tablets

- Temporarily relieves symptoms due to common cold hay fever or other allergies affecting the upper respiratory tract.
- Runny nose
- Sneezing
- Itchy watery eyes
- Itching of the nose or throat





Drug Facts	Drug Facts (continued)	
Active ingredient (in each tablet) Purpose Diphenhydramine hydrochloride 25 mgAntihistamine	Consult your doctor if you have ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland.	
Uses ■ temporarily relieves symptoms due to common cold, hay fever or other allergies affecting the upper respiratory tract ■ runny nose ■ sneezing ■ Itchy watery eyes ■ Itching of the nose or throat.		
Warnings Do not use ■ to make a child sleepy ■ with any other product	If Pregnant or breast-feeding, ask a health professional before use.	
containing diphenhydramine, even one used on skin.	Keep out or reach of children.	

Drug Facts (continued)		Drug Facts (contin	ued)
In case of overdose, get medical help or concenter right away.	tact a poison control	Children 6 to 12 years of age	1 tablet
When using this product	0 ,		do not use this product in children under 6 years
Directions: ■ take every 4 to 6 hours ■ do not take more than 6 doses in 24 hours			
Adult and children 12 years of age and over	1 to 2 tablets	moisture	

Drug Facts (continued)

Inactive ingredients

carnauba wax, colloidal anhydrous silica, croscarmellose sodium, dibasic calcium phosphate, hydroxy propyl methyl cellulose phthalate HP-55, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, polysorbate 80, polyvinyl alcohol, talc, titanium dioxide, xanthan gum,



Manufactured by: SIMPEX PHARMA PVT. LTD. C-7 to C-13 and C-59 to C-64, Siggadi Growth Center (SIDCUL), Siggadi, Kotdwar-246149, District Pauri Garhwal, Ultrakhand, India.

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76457-002
Route of Administration	ORAL		

Active Ingredient/Active Moiet	У
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Ingredient Name Basis of Strength Strength

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

(DIPHENHYDRAMINE - UNII:8GTS82S83M)

DIPHENHYDRAMINE HYDROCHLORIDE

25 mg

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POLYSORBATE 80 (UNII: 60ZP39ZG8H)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
XANTHAN GUM (UNII: TTV12P4NEE)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

Product Characteristics			
Color	white (white)	Score	no score
Shape	ROUND (round)	Size	8mm
Flavor		Imprint Code	;
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76457-002- 00	1 in 1 CARTON	02/09/2018	
1		100 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 Drug	M012	02/09/2018	

Labeler - Simpex Pharma Pvt. Ltd (916758275)

Registrant - Simpex Pharma Pvt. Ltd (916758275)

Establishment			
Name	Address	ID/FEI	Business Operations

Simpex Pharma Pvt. Ltd 916758275 manufacture(76457-002)

Revised: 11/2023 Simpex Pharma Pvt. Ltd