

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet**  
**Simpex Pharma Pvt. Ltd**

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**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:**

**SIMPEX**

**100 Tablets**



**Antihistamine  
DIPHENHYDRAMINE  
HYDROCHLORIDE**

**Anti-Allergy 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

Do Not Use if Impressed Safety Seal Under Cap Is Broken Or Missing.



Distributed by:

Lot No.: \_\_\_\_\_  
Mfg. Date: \_\_\_\_\_  
Exp. Date: \_\_\_\_\_

**PEAL**

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b> Diphenhydramine hydrochloride 25 mg.....Antihistamine</p> <p><b>Purpose</b> Antihistamine</p> <p><b>Uses</b> ■ 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.</p> <p><b>Warnings</b> <b>Do not use</b> ■ to make a child sleepy ■ with any other product containing diphenhydramine, even one used on skin. ▶</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Consult your doctor if you have</b> ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland.</p> <p><b>Consult your doctor if you are taking sedatives or tranquilizers</b> ■ sedative, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur especially in children.</p> <p><b>If Pregnant or breast-feeding, ask a health professional before use.</b></p> <p><b>Keep out or reach of children.</b> ▶</p>
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<p><b>Drug Facts (continued)</b></p> <p>In case of overdose, get medical help or contact a poison control center right away.</p> <p><b>When using this product</b> ■ marked drowsiness may occur ■ avoid alcoholic drinks.</p> <p><b>Directions:</b> ■ take every 4 to 6 hours ■ do not take more than 6 doses in 24 hours</p> <p>Adult and children 12 years of age and over   1 to 2 tablets ▶</p>	<p><b>Drug Facts (continued)</b></p> <table border="1"> <tr> <td>Children 6 to 12 years of age</td> <td>1 tablet</td> </tr> <tr> <td>Children under 6 years of age</td> <td>do not use this product in children under 6 years</td> </tr> </table> <p><b>Other Information</b> ■ each tablet contains : Calcium 25 mg / tablet ■ store at room temperature 15°-30° (59 °-86 °F) ■ protect from light and moisture ▶</p>	Children 6 to 12 years of age	1 tablet	Children under 6 years of age	do not use this product in children under 6 years
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Children under 6 years of age	do not use this product in children under 6 years				

<p><b>Drug Facts (continued)</b></p> <p><b>Inactive ingredients</b> 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, ▶</p>	 <p>Manufactured by: <b>SIMPEX PHARMA PVT. LTD.</b> C-7 to C-13 and C-59 to C-64, Siggadi Growth Center (SIDCUL), Siggadi, Kotdwar-246149, District Pauri Garhwal, Uttarakhand, India.</p>
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<b>DIPHENHYDRAMINE HYDROCHLORIDE</b>			
diphenhydramine hydrochloride tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76457-002
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

### Product Characteristics

<b>Color</b>	white (white)	<b>Score</b>	no score
<b>Shape</b>	ROUND (round)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	;
<b>Contains</b>			

### 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
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Revised: 11/2023

Simpex Pharma Pvt. Ltd