DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet
Simpex Pharma Pvt. Ltd

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 hydrochloride

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
- Ichy watery eyes
- Iching of the nose or throat.

Warnings

Keep outer carton for complete warning and product information.

Do not use

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

Consult a doctor

if you have

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

if you are taking sedatives or tranquilizers

- sedative, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability my occur especially in children.

Pregnancy or breast feeding

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.

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
- Children under 4 years of age - **do not use**

Other Information

- each tablet contains: Calcium 25 mg/tablet
- store at room temperature 15 to 30 degrees Celsius (59 degrees to 86 degrees Fahrenheit)
- protect from light and moisture
- do not use if imprented safety seal under cap is broken or missing.

Inactive ingredient

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose, lecithin*, magnesium stearate, microcrystalline cellulose, opadry AMB white*, polyethylene glycol (PEG) 400, polysorbate 80, polyvinyl alcohol*, purified water*, talc*, and titanium dioxide. *contains one or more of these ingredients.

Questions or comments?

Call toll free:

Package Label

Antihistamine 100 tablets

Diphenhydramine hydrochloride

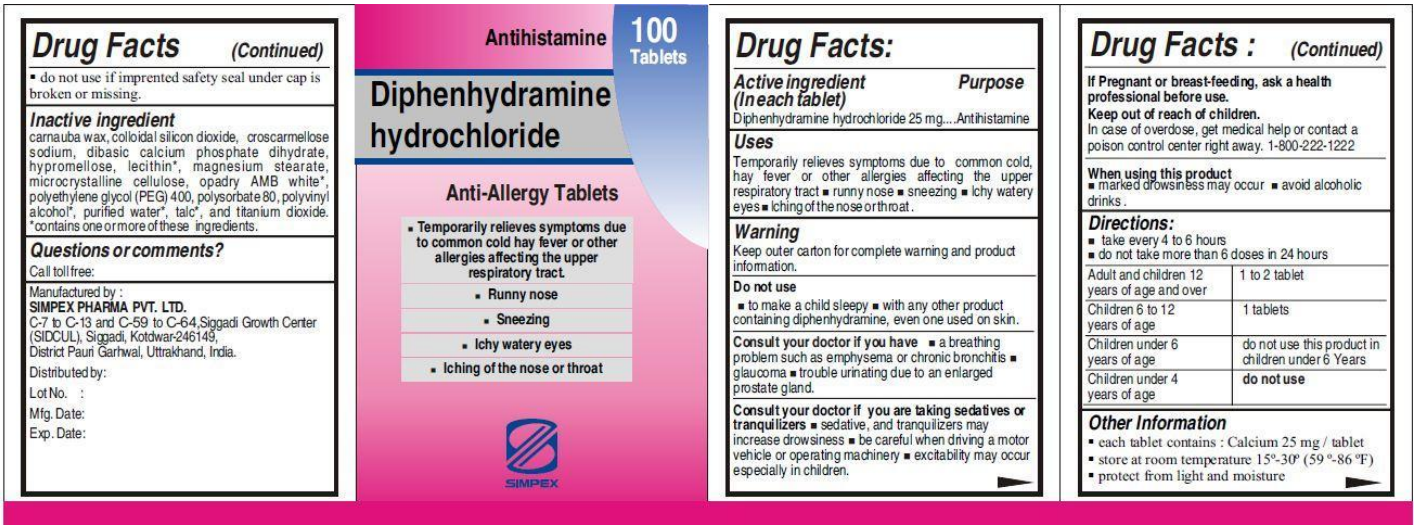
Anti-Allergy Tablets

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

SIMPEX

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, Uttrakhand, India
Distributed by:
Lot. No. :
Mfg.Date:
Exp.Date:



Drug Facts (Continued)

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Antihistamine

100 Tablets

Diphenhydramine hydrochloride

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■ 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.

Drug Facts : (Continued)

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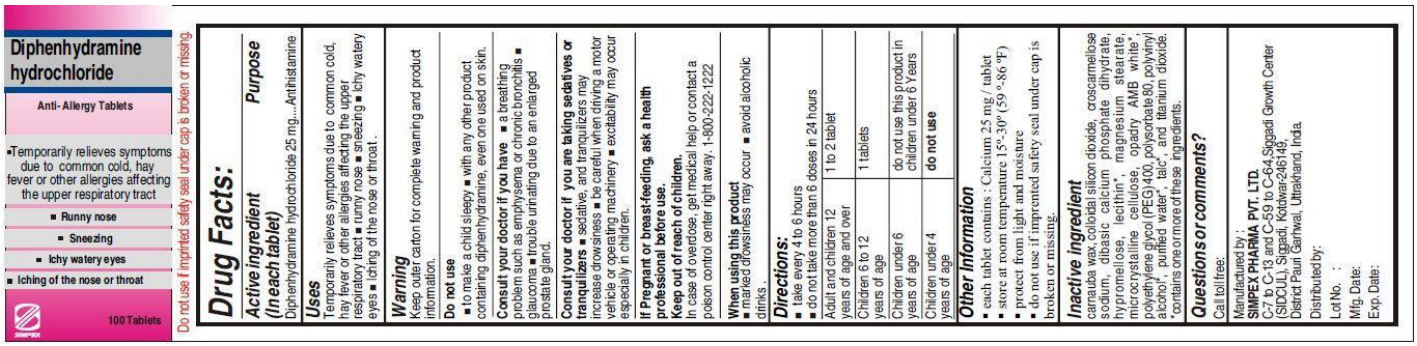

Diphenhydramine hydrochloride
Anti- Allergy Tablets
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DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE -	DIPHENHYDRAMINE	25 mg

UNII:8GTS82S83M)	HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
WATER (UNII: 059QF0KO0R)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76457-002-00	1 in 1 CARTON		
1		100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/15/2012	

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)