

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet, film coated

HIMPRIT PHARMACHEM 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 HCL TABLETS 25 mg PINK

Drug Facts

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
 - itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing

Warnings

Do not use with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- avoid alcoholic drinks
- excitability may occur, especially in children

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

Keep out of reach of children.

Directions

- take every 4 to 6 hours
- do not take more than 6 times in 24 hours

adults and children 12 years and over	1 to 2 tablets
children 6 to under 12 years	1 tablet
children under 6 years	do not use this product in children under 6 years of age

PRINCIPAL DISPLAY PANEL - 25 mg Label**DIPHENHYDRAMINE HCL TABLETS 25 mg PINK****Each Film coated Tablet Contains:**

DIPHENHYDRAMINE HCL 25 MG

Lot No :	Jar No. :
MFG. :	Quantity : 100,000 Tablets
DATE :	NDC. No : 65437-036-10
Exp. Date :	

WARNING :**KEEP OUT OF THE REACH OF CHILDREN**

STORE CONTROLLED ROOM TEMPRATURE OF 59° –86°F (15° – 30°C)

PROTECT FROM LIGHT, MOISTURE AND FREEZING

THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY.

CONTENTS SHOULD BE APPROVED,REPACKAGED IMMEDIATELY AND LABELED IN STRICT

CONFORMANCE WITH THE FDA AND REGULATIONS THEREUNDER

MANUFACTURED BY:

MANUFACTURED CODE No Guj/Drugs/G/1362

LABELER CODE # 14803

MANUFACTURED FOR:

HIMPRIT PHARMACHEM PVT. LTD

"LAKULISH", R.V.DESAI ROAD,

NEXT TO NAVAPURA POLICE STATION

BARODA, INDIA – 390 001

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

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DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65437-036
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	PINK	Score	no score
Shape	OVAL (CAPSULE-SHAPED)	Size	10mm
Flavor		Imprint Code	S4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65437-036-05	1 in 1 DRUM		
1		50000 in 1 BAG		
2	NDC:65437-036-07	1 in 1 DRUM		
2		75000 in 1 BAG		
3	NDC:65437-036-10	1 in 1 DRUM		
3		100000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/01/2010	

Labeler - HIMPRIT PHARMACHEM PVT LTD (917261992)

Revised: 2/2010

HIMPRIT PHARMACHEM PVT LTD