

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 BLUE

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep aid

Use

relief of occasional sleeplessness

Warnings

Do not use

- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

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

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

When using this product

- avoid alcoholic drinks
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

- sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

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

Keep out of reach of children.

Overdose warning: In case of overdose get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 caplets at bedtime if needed or as directed by a doctor
children under 12 years	do not use

Other information

- each caplet contains: **calcium 20 mg**
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or blister unit is broken**
- see side panel for lot number and expiration date

Inactive ingredients

carnauba wax, cellulose, croscarmellose sodium dibasic calcium phosphate, FD&C blue #1, hypromellose, magnesium stearate, polyethylene glycol, polysorbate 80, titanium dioxide

PRINCIPAL DISPLAY PANEL - 25 mg Label

DIPHENHYDRAMINE HCL TABLETS 25 mg BLUE

Each Film coated Tablet Contains:

DIPHENHYDRAMINE HCL 25 MG

Lot No	:	Jar No.	:
MFG.	:	Quantity	: 100,000 Tablets
DATE	:	NDC. No	: 65437-037-10
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"

DIPHENHYDRAMINE HCL TABLETS 25 mg BLUE

Each Film coated Tablet Contains:

DIPHENHYDRAMINE HCL 25 MG

Lot No	:		Jar No.	:	
MFG. DATE	:		Quantity	:	100,000 Tablets
Exp. Date	:		NDC. No	:	65437-037-10

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"

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65437-037
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: 059QF0KO0R)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL (CAPSULE-SHAPED)	Size	10mm
Flavor		Imprint Code	S5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65437-037-05	1 in 1 DRUM		
1		50000 in 1 BAG		
2	NDC:65437-037-07	1 in 1 DRUM		
2		75000 in 1 BAG		
3	NDC:65437-037-10	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	part338	03/01/2010	

Labeler - HIMPRIT PHARMACHEM PVT LTD (917261992)

Revised: 2/2010

HIMPRIT PHARMACHEM PVT LTD