

DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule, liquid filled
Softech 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 HCl 25 mg

Drug Facts

Active Ingredient in each Softgel

Diphenhydramine HCl 25 mg

Purpose

Nighttime sleep-aid

Keep out of reach of Children

Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not use

- for children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- with other drugs that causes drowsiness such as antihistamines & nighttime cold/flu products

Directions

Take only one dose per day (24 hours) - see Overdose warning

adults & children 12 yrs & over One dose = Two 25 mg Softgels (50 mg) at bedtime if needed or as directed by a doctor

Other Information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F) and high humidity
- protect from light

Inactive Ingredients

FD&C blue#1, FD&C red#40, gelatin, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, sorbitol, titanium dioxide

Principal Display Panel

Diphenhydramine Hydrochloride Capsules, USP 25 mg

Diphenhydramine Hydrochloride Capsules, USP 25 mg	
Each Capsule Contains: Diphenhydramine HCl USP 25 mg	
Lot No.:	Bag No. :
Mfg Date:	Quantity : 5000 Capsules
Exp. Date:	NDC Code : 48769-060-99
WARNING: DO NOT USE	
<ul style="list-style-type: none"> • FOR CHILDREN UNDER 12 YEARS OF AGE • WITH ANY OTHER PRODUCT CONTAINING DIPHENHYDRAMINE, EVEN ONE USED ON SKIN • WITH OTHER DRUGS THAT CAUSES DROWSINESS SUCH AS ANTIHISTAMINES & NIGHTTIME COLD/FLU PRODUCTS 	
STORE AT 20-25°C (68-77°F), AVOID EXCESSIVE HEAT ABOVE 40°C (104°F) AND HIGH HUMIDITY ,PROTECT FROM LIGHT	
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELLED IN STRICT CONFORMANCE WITH THE FDA AND REGULATIONS THEREUNDER.	
Manufactured By: Softech Pharma Pvt. Ltd.	Manufactured For:
MANUFACTURER CODE No.: DD/417 LABELLER CODE # 48769	Raritan Pharmaceuticals 8 Joanna Court, East Brunswick, NJ 08816
CAUTION: " FOR MANUFACTURING, PROCESSING OR REPACKING	

DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48769-060
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
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	

GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	purple	Score	no score
Shape	capsule	Size	7mm
Flavor		Imprint Code	R60
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48769-060-99	5000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	01/01/2013	

Labeler - Softech Pharma Pvt. Ltd (677111277)

Establishment

Name	Address	ID/FEI	Business Operations
Softech Pharma Pvt. Ltd		677111277	manufacture(48769-060)

Revised: 12/2012

Softech Pharma Pvt. Ltd