DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule, liquid filled
SPIRIT PHARMACEUTICALS,LLC

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 Soft Gelatin Capsules

Drug Facts

Active ingredients (in each LiquiCap)

Diphenhydramine HCl 50 mg

Purpose

Nighttime Sleep aid

Uses

For relief occasional sleeplessness

Warnings

Do not use

- for 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

- Glaucoma
- trouble urinating due to enlarged postage gland
- a breathing problem such as emphysema or chronic bronchitis

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

When using this product avoid alcoholic drinks

Stop use and ask 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.

In case of overdose,get medical help or contact a poison control center right away.

Direction

adults and children 12 years of age and older -1 softgel (50mg) at bedtime if needed; or as directed by doctor

Inactive ingredients

PEG – 400, Propylene Glycol USP , Gelatin , Sorbitol, FD & C Blue No.1 IH, Purified water

PRINCIPAL DISPLAY PANEL - 50 mg Shipper Label

Diphenhydramine Hydrochloride Soft Gelatin Capsules

Each soft gelatin capsule contains:
Diphenhydramine Hydrochloride USP 50 mg

LOT NO :

MFG DATE :

EXP. DATE :

NDC NO : 68210-1510-4

QUANTITY : 1000 × 4 Capsules

GROSS WT. :

WARNING:
KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED ROOM TEMPERATURE OF 59° - 86°F (15° - 30°C)
PROTECT FROM LIGHT, MOISTURE AND FREEZING

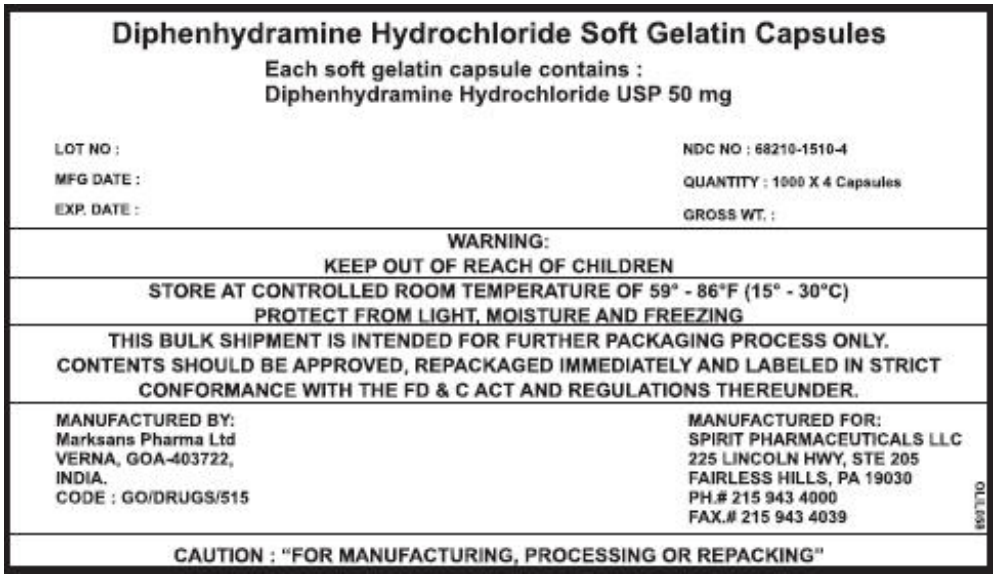
THIS BULK SHIPMENT IS INTENDED FOR FURTHER PACKAGING PROCESS ONLY. CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT
CONFORMANCE WITH THE FD & C ACT AND REGULATIONS THEREUNDER.

MANUFACTURED BY:
Marksans Pharma Ltd
VERNA, GOA-403722,
INDIA.
CODE : GO/DRUGS/515

MANUFACTURED FOR:
SPIRIT PHARMACEUTICALS LLC
225 LINCOLN HWY, STE 205
FAIRLESS HILLS, PA 19030
PH.# 215 943 4000
FAX.# 215 943 4039

CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKING"

OLIL058



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-1510
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	293
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1510-4	1 in 1 DRUM		
1		4000 in 1 BAG		
2	NDC:68210-1510-6	1 in 1 DRUM		
2		6000 in 1 BAG		
3	NDC:68210-1510-8	1 in 1 DRUM		
3		8000 in 1 BAG		
4	NDC:68210-1510-1	1 in 1 DRUM		
4		10000 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part338	06/01/2010	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Revised: 7/2010 SPIRIT PHARMACEUTICALS,LLC