

NIGHTTIME SLEEP AID - diphenhydramine capsule, liquid filled

Agile Pharmachem

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 50mg, USP

Active Ingredient

(in each softgel)

Diphenhydramine HCl 50 mg

Purpose

Nighttime sleep aid

Uses

- For relief of occasional sleeplessness.

Directions

- **adults and children 12 years and over** : one softgel (50 mg) at bed time if needed or as directed by a doctor.
- **children under 12 years:do not use**

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

- glaucoma
- trouble urinating due to an enlarged prostate 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

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)

Other Information

- save carton for full directions and warnings

Inactive Ingredients

Blue 1, gelatin, glycerin, polyethylene glycol, polyvinyl acetate phthalate, propylene glycol, sorbitol,


titanium dioxide and water.

Questions or Comments

Call 1-855-314-1850

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Diphenhydramine Hydrochloride 50 mg soft gelatin Capsules			
Each soft gelatin capsule Contains: Diphenhydramine Hydrochloride USP 50 mg Excipients - QS			
BATCH NO.		QUANTITY	50X750 <u>softgels</u>
MFG.DATE		SHIPPER NO.	___ out of ___
EXP.DATE		GROSS WT.	
-	-	NET WT.	
WARNING: KEEP OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)	
CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: MEDGEL PRIVATE LIMITED 19-20, SEZ, PHARMA ZONE, PHASE-II, PITHAMPUR, DISTT. DHAR-454775		DISTRIBUTED BY: AGILE PHARMACHEM 116D, SHIROMANI COMPLEX SATELLITE, AHMEDABAD-380015	
MFG. LIC. NO.	MP/DRUGS/25/4/2011	MFG. LIC. NO.	GJ-AD2-98783
LABELLER CODE	51344	NDC No.	58805 -006-00
SHIPPED TO: VELOCITY PHARMA LLC 226/B, SHERWOOD AVE, FARMINGDALE, NY-11735			
LABELLER CODE	76168		



Diphenhydramine Hydrochloride 50 mg soft gelatin Capsules			
Each soft gelatin capsule Contains: Diphenhydramine Hydrochloride USP 50 mg Excipients - QS			
BATCH NO.		QUANTITY	30X750 softgels
MFG.DATE		SHIPPER NO.	___ out of ___
EXP.DATE		GROSS WT.	
-	-	NET WT.	
WARNING: KEEP OUT OF THE REACH OF CHILDREN		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86°F (15°C to 30°C)	
CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: MEDGEL PRIVATE LIMITED 19-20, SEZ, PHARMA ZONE, PHASE-II, PITHAMPUR, DISTT. DHAR-454775		DISTRIBUTED BY: AGILE PHARMACHEM 116D, SHIROMANI COMPLEX SATELLITE, AHMEDABAD-380015	
MFG. LIC. NO.	MP/DRUGS/25/4/2011	MFG. LIC. NO.	GJ-AD2-98783
LABELLER CODE	51344	NDC No.	58805 -006-01
SHIPPED TO: VELOCITY PHARMA LLC 226/B, SHERWOOD AVE, FARMINGDALE, NY-11735			
LABELLER CODE	76168		



DIPHENHYDRAMINE HYDROCHLORIDE SOFTGEL CAPSULE, USP 50 MG
NDC:58805-006-00 Softgel Liquid filled

NIGHTIME SLEEP AID			
diphenhydramine capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58805-006
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
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)			
GELATIN (UNII: 2G86QN327L)			

GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
SORBITOL (UNII: 506T60A25R)	
POLYVINYL ACETATE PHTHALATE (UNII: 58QVG85GW3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	206
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58805-006-00	750 in 1 BOX		
1		1 in 1 BAG		
2	NDC:58805-006-01	750 in 1 BOX		
2		30 in 1 BAG		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/31/2014	

Labeler - Agile Pharmachem (650687853)

Registrant - Agile Pharmachem (650687853)

Revised: 3/2015

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