

## **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.*

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### **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

<b>Diphenhydramine Hydrochloride 50 mg soft gelatin Capsules</b>			
<b>Each soft gelatin capsule Contains:</b> Diphenhydramine Hydrochloride USP 50 mg Excipients - QS			
BATCH NO.	M16DN004	QUANTITY	48X750 softgels
MFG.DATE	02/2016	SHIPPER NO.	_____ out of _____
EXP.DATE	01/2018	GROSS WT.	
-	-	NET WT.	
<b>WARNING:</b> 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	
<b>MANUFACTURED BY:</b> MEDGEL PRIVATE LIMITED 19-20, SEZ, PHARMA ZONE, PHASE-II, PITHAMPUR, DISTT. DHAR-454775		<b>DISTRIBUTED BY:</b> 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 -006-02
<b>SHIPPED TO:</b> VELOCITY PHARMA LLC 226/B, SHERWOOD AVE, FARMINGDALE, NY-11735			
LABELLER CODE	76168		



## DIPHENHYDRAMINE HYDROCHLORIDE SOFTGEL CAPSULE, USP 50 MG

NDC:58805-006-02

<b>NIGHTIME SLEEP AID</b>			
diphenhydramine capsule, liquid filled			
<b>Product Information</b>			
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: H3R47K3TBD)	
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:58805-006-02	750 in 1 BAG	09/30/2014	
1		48 in 1 BOX; Type 0: Not a Combination Product		

**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)

Revised: 5/2018

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