

DIPHENHYDRAMINE HCL - diphenhydramine hcl 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.

Drug Facts

Active Ingredient

(in each capsule)

Diphenhydramine HCl 25mg

Purpose

Sleep Aid

Uses

- For the relief of occasional sleeplessness
- Reduces time to fall asleep if have difficulty falling asleep

Warnings

Do not use

- If children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin
- with other drug that cause drowsiness such as antihistamines and nighttime cold/flu products
- Do not use with generic NyQuil®

Ask a doctor before use if you have:

- A breathing problem such as asthma, emphysema, or Chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- heart disease
- You are taking a diuretic

Ask a doctor or pharmacist before use if you are taking sedative or tranquilizers or any other sleep-aid, when using this product :

- Avoid alcoholic beverages and other drugs that cause drowsiness
- Drowsiness will occur
- Be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if sleeplessness persists continuously for more than two 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: Taking more than directed can cause serious health problems, In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

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

Adults and Children 12 years and over

- One Dose = Two 25 mg LiquiCaps (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 No. 1, FD&C Red No. 40, Gelatin, Glycerin, Polyethylene Glycol, Purified Water, Sorbitol, Titanium Dioxide


Questions?

Call 1-855-314-1850

TAMPER EVIDENT: This Package is safety sealed & child resistant. Use only if blisters are intact. If difficult to open, use scissors.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<u>Diphenhydramine HCl 25mg soft gelatin capsules</u>			
<u>Each soft gelatin capsule contains:</u> Diphenhydramine HCl USP 25mg			
BATCH NO. :		QUANTITY :	12X25X12 softgels
MFG.DATE :		SHIPPER NO. :	
EXP.DATE :		GROSS WT. :	
NDC NO :	58805 -001-14	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)			
PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING			
CONFORMANCE WITH THE F.D & C. ACT AND REGULATIONS THEREUNDER.			
DISTRIBUTED BY: AGILE PHARMACHEM 116D, SHIROMANI COMPLEX SATELLITE, AHMEDABAD-380015		DISTRIBUTED TO: VELOCITY PHARMA LLC 226/B, SHERWOOD AVE, FARMINGDALE, Ny-11735	
LABELLER CODE :	58805	LABELLER CODE :	76168
MFG. LIC. NO. :	GJ-AD2-98783		



NDC: 58805-001-14 LIQUID GELS**DIPHENHYDRAMINE HCL**

diphenhydramine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58805-001
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: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	602
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58805-001-14	3600 in 1 BLISTER PACK		
1		1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/15/2013	

Labeler - Agile Pharmachem (650687853)

