DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet Pharmacy Value Alliance, 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.

Sleep-Aid Diphenhydramine HCl USP, 25 mg NIGHTTIME SLEEP AID

Active ingredient

(in each gelcap) Diphenhydramine HCl USP, 25 mg

Purpose

Nighttime sleep-aid

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 cause drowsiness such as antihistamines and nighttime cold/flu products

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

Ask a doctor or pharmacist before use if you are

taking sedatives 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 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

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 & children 12 years and over

2 gelcaps at bedtime if needed or as directed by a doctor

Other information

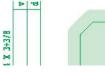
- store at 20°-25°C (68°-77°F). See USP Controlled Temperature.
- avoid high humidity

Inactive ingredients

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C red # 28, D&C red # 33, dicalcium phosphate dihydrate, FD&C blue #1, FD&C yellow #6 gelatin, hydroxyl propyl cellulose, hypromellose, iron oxide red, iron oxide yellow, isopropyl alcohol, lecithin, magnesium stearate, microcrystalline cellulose, n-butyl alcohol, polyethylene glycol, polyvinyl alcohol, propylene glycol, shellac, talc, titanium dioxide, xanthan gum

Questions or comments?

call **1-877-770-3183** Mon-Fri 9:00 AM to 4:30 PM EST.







DIPHENHYDRAMINE HYDROCHLORIDE							
diphenhydramine hydrochloride tablet							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-789				
Route of Administration	ORAL						

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Active 1	ngredient	Active Moiety			
		Ingredient Name	Basis of St	•	Strength
DIPHENHY UNII:8 GTS		IYDRO CHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRA	MINE - DIPHENHYDRAMIN HYDROCHLORIDE	E 2	25 mg
Inactive	Ingredie	nts			
		Ingredient Name		Stre	ength
D&C RED	NO.33 (UNI	I: 9DBA0SBB0L)			
AMMO NL	A (UNII: 51380	Q19F1X)			
		OSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
		(UNII: H77VEI93A8)			
FERRIC O	XIDE RED (U	JNII: 1K09F3G675)			
		TE (UNII: 70097M6I30)			
		NII: 8 PJ6 1P6 TS3)			
	(UNII: 46 N10	,			
		TTV12P4NEE)			
		COL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
		L, UNSPECIFIED (UNII: 532B59J990)			
	III: 7SEV7J4R				
		III: H3R47K3TBD)			
	(UNII: 2G86C				
		ELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)			
		NII: 3NXW29V3WO)			
		DW (UNII: EX438O2MRT)			
		VII: ETJ7Z6XBU4)			
		SODIUM (UNII: M28OL1HH48)			
	,	I: 767IP0 Y5NH)			
		IDE (UNII: XM0 M8 7F357)			
		L (UNII: ND2M416302)			
		(UNII: 1DI56QDM62)			
		CRYSTALLINE (UNII: OP1R32D61U)			
		(UNII: 6DC9Q167V3)			
TITANIUN	1 DIO XIDE (U	JNII: 15FIX9V2JP)			
Product	Characte	ristics			
Color	gray (Encaps shells)	ulated gray color tablets with blue gray opaque and purple	opaque hard gelatin	Score	no score
Shape	OVAL			Size	16 mm
Flavor				Imprint Code	G15
Contains					
Packagi	ng				
-	n Code	Package Description	Marketing Start Date	Marketing F	nd Date
., Itcl		r uchage Description		Line the Line Li	Dutt

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part338	0 3/15/20 19					

Labeler - Pharmacy Value Alliance, LLC (101668460)

Revised: 1/2021

Pharmacy Value Alliance, LLC