

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.



size : 1+3/4 X 1+3/4
 ref # : 02100004B
 material : 0101 SBS



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-789
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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
AMMONIA (UNII: 5138Q19F1X)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FERROUS FERRIC OXIDE (UNII: XM0M87F357)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	gray (Encapsulated gray color tablets with blue gray opaque and purple opaque hard gelatin shells)	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	G15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-789-48	48 in 1 BOTTLE; Type 0: Not a Combination Product	03/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	03/15/2019	

Labeler - Pharmacy Value Alliance, LLC (101668460)

Revised: 1/2021

Pharmacy Value Alliance, LLC