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.

Nighttime Sleep-Aid
Diphenhydramine HCl USP, 50 mg
NIGHTTIME SLEEP-AID
Rapid Release

Active ingredient

(in each gelcap)

Diphenhydramine HCl USP 50 mg

Purpose

Nighttime sleep-aid

Uses

■ for relief of occasional sleeplessness

Warnings

Do Not Use

■ for 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

■ a breathing problem such as emphysema, or chronic bronchitis

■ glaucoma

■ difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

■ avoid alcoholic beverages

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 the reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults & children 12 years of age and over: 1 gelcap (50 mg) 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

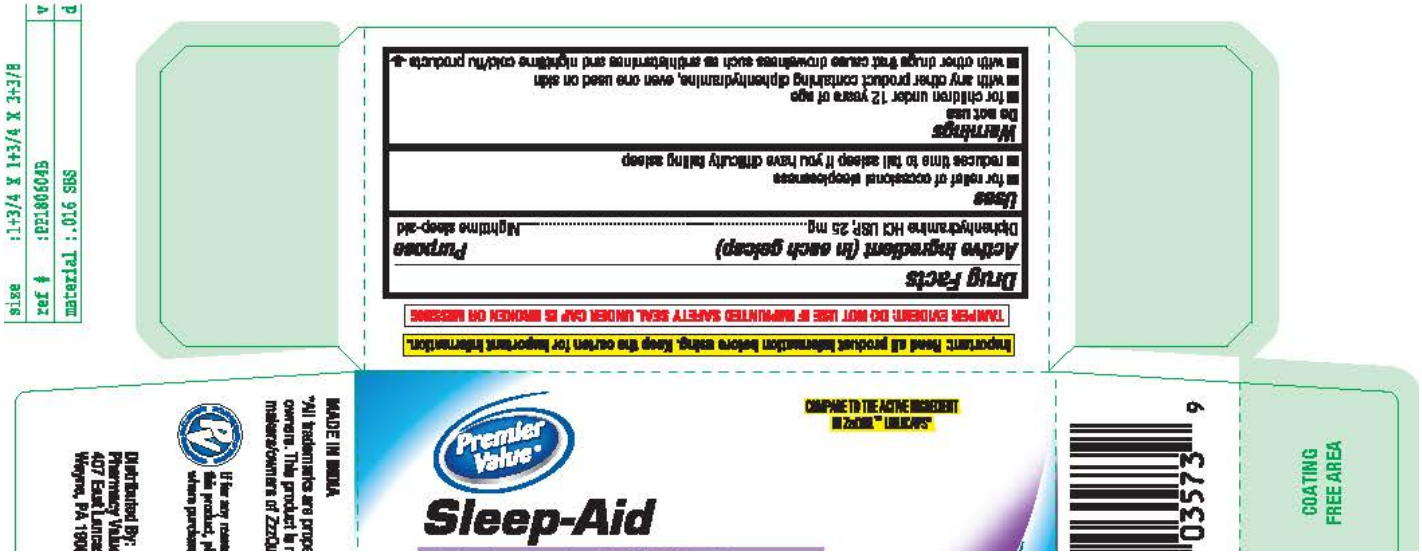
Inactive ingredients

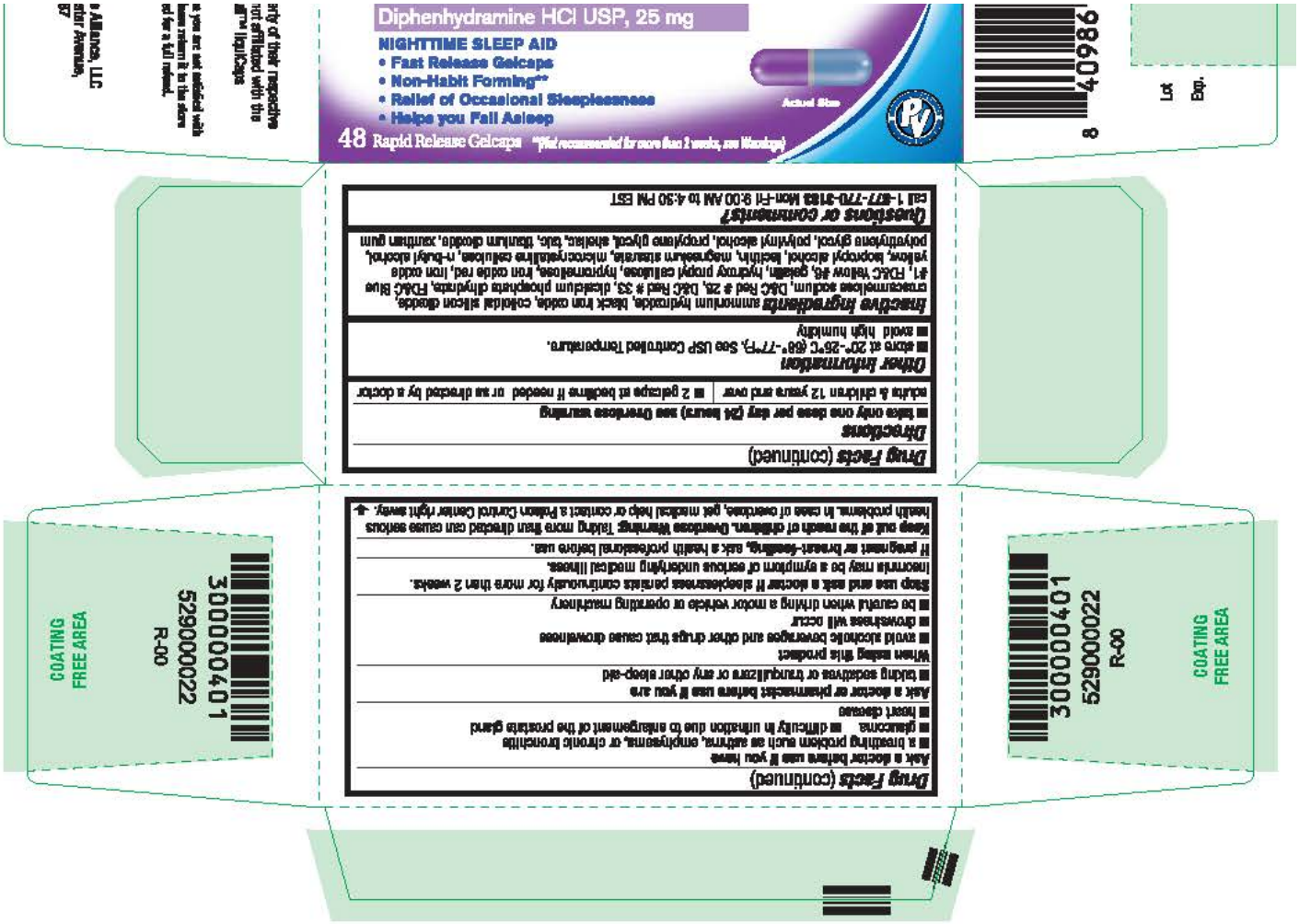
ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C red #33, dicalcium phosphate dihydrate, FD&C blue #1, FD&C yellow #6, gelatin, hydroxy propyl cellulose, hypromellose, isopropyl alcohol, lecithin, magnesium stearate, microcrystalline cellulose, n-butyl alcohol, 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 HCl 50 mg RR Gelcaps





DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-795
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**

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TALC (UNII: 7SEV7J4R1U)	
AMMONIA (UNII: 5138Q19F1X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	white (Encapsulated white color tablet with blue gray opaque and light blue opaque hard gelatin shells)	**Score**	no score
Shape	OVAL	**Size**	16mm
Flavor		**Imprint Code**	G16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-795-48	48 in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	04/01/2018	

Labeler - PHARMACY VALUE ALLIANCE, LLC (101668460)

Revised: 1/2021 PHARMACY VALUE ALLIANCE, LLC