

DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule, liquid filled capsule, liquid filled AMZ789 LLC

Diphenhydramine HCl 25 mg

Diphenhydramine HCl 25 mg

Nighttime sleep-aid

for the relief of occasional sleeplessness

reduces time to fall asleep if you have difficulty falling asleep

Warnings

- 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
- do not use with NyQuil

- 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

- 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. 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.

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

adults & Children 12 yrs & over	One dose = TWO 25mg softgels (50mg) at bedtime if needed or as directed by a doctor
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FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, purified water, sorbitol special and white edible ink

RxZell®
Nighttime SleepAid
 Diphenhydramine HCl 25mg

- Non Habit-Forming
- Fast Acting



220
Softgels

*Compare to the active ingredient in ZzzQuil®

Drug Facts	
Active ingredient (in each softgel) Diphenhydramine HCl 25mg.....	Purpose Nighttime sleep-aid
Use ■ 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 products containing diphenhydramine, even one used on skin ● with other drugs that cause drowsiness such as antihistamines and nighttime cold/flu products ● do not use with NyQuil	
Ask a doctor before use if you have ● a breathing problem such as emphysema or chronic bronchitis ● glaucoma ● trouble urinating due to an enlarged 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 a serious underlying medical illness	
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.	
Directions	
● Take only one dose per day (24 hour)	
● Adults and children 12 years of age and over: One dose = Two softgels (25mg) at bedtime if needed, or as directed by a doctor	
Other information	
■ store between 59-86°F (15-30°C) ■ avoid excessive heat above 104°F (40°C) ■ protect from light	
Inactive ingredients FD&C blue #1, FD&C red #40, gelatin, glycerin polyethylene glycol, purified water, sorbitol solution, white ink	
*This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks ZzzQuil® and LiquiCaps®. Distributed by: AMZ789, LLC., Smithtown, NY, 11787	

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule, liquid filled capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73629-007
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
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	purple	Score	score with uneven pieces
Shape	CAPSULE (Oblong)	Size	15mm
Flavor		Imprint Code	PC11
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73629-007-22	220 in 1 BOTTLE; Type 0: Not a Combination Product	10/18/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	10/18/2023	

Labeler - AMZ789 LLC (117410213)

Revised: 1/2024

AMZ789 LLC