DIPHENHYDRAMINE HYDROCHLORIDE 50MG- diphenhydramine hydrochloride 50mg capsule, liquid filled
AMZ789 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.

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diphenhydramine HCl 50mg softgels

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Use

For relief of occasional sleeplessness

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Warnings

for children under 12 years of age

with any other products containing diphenhydramine, even one used on skin

Ask a doctor or pharmacist before use if

you have a breathing problem such as emphysema or chronic bronchitis, glaucoma, trouble urinating due to an enlarged prostate gland

you are taking sedatives or tranquilizers

When using this product

avoid alcholic drinks

Stop use and ask a doctor if

sleeplessness presists continuously for more than 2 weeks. Insomnic may be a symptom of a series underlying medical illness

If pregnant or breast-feeding

ask a health professional before use

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Direction

adults and children 12 years and over: 1 softgel at bedtime if needed, or as directed by a doctor

FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol sorbitan solution, white ink

RxZell

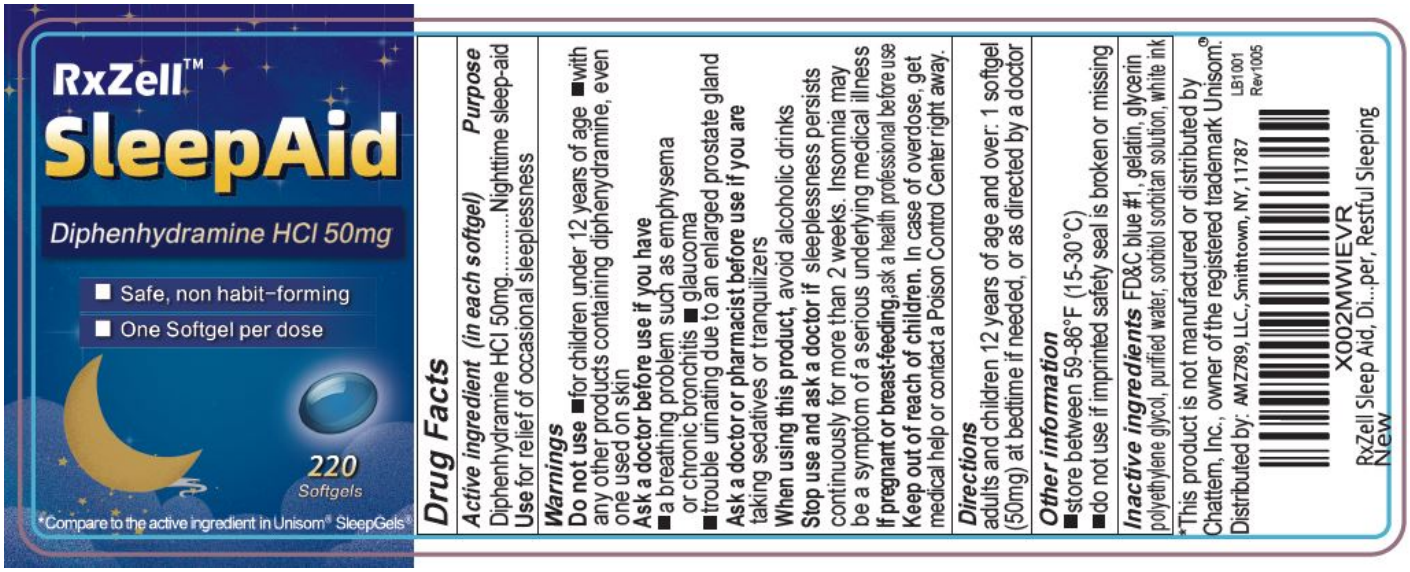
SleepAid

Dyphenhydramine HCl 50mg

Non Habit-Forming

Easy to Swallow

Package.Label Principal Display Panel



DIPHENHYDRAMINE HYDROCHLORIDE 50MG

diphenhydramine hydrochloride 50mg capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73629-001
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**
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN (UNII: 2G86QN327L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue (clear)	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	PC13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73629-001-22	220 in 1 BOTTLE; Type 0: Not a Combination Product	09/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	09/21/2020	

Labeler - AMZ789 LLC (117410213)

Establishment

Name	Address	ID/FEI	Business Operations
Nutra-Med Packaging Inc.		022004902	pack(73629-001)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(73629-001) , analysis(73629-001)

Revised: 1/2022 AMZ789 LLC