SLEEP AID- diphenhydramine hcl 25 mg tablet Pioneer Life Sciences, 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.

Active Ingredient

Diphenhydramine Hcl 25mg

Purpose

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 with other drugs that cause drowsiness

Ask Doctor:

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

ASK DOCTOR/PHARMACIST:

Ask a doctor or pharmacist before use if you aretaking sedatives or tranquilizers.

WHEN USING THIS PRODUCT

drowsiness will occur avoid alcoholic drinks do not drive a motor vehicle or operating machinery

PREGNANCY

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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

DIRECTIONS

do not take more than directed (see overdose warning)

adults and children 12 years of age and over: - take 2 caplets at bedtime if needed, or as directed by a doctor

children under 12 years of age: do not use

OTHER INFORMATION

each caplet contains: calcium 15 mg store between 20°-25°C (68°-77°F); avoid high humidity protect from light read all product information before using

INACTIVE INGREDIENTS

dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, opadry II

QUESTIONS OR COMMENTS?

Call 1-732-698-5070 Monday through Friday 9AM–5PM EST or www.pioneerlifesciences.com

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.

PRINCIPAL DISPLAY PANEL



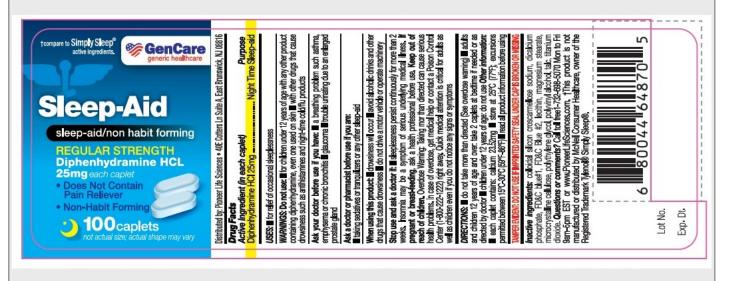
SLEEP AID diphenhydramine hcl 25 mg tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:72090-020 Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients		
Ingredient Name	Strength	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)		

Product Characteristics				
Color	blue	Score	no score	
Shape	CAPSULE	Size	11mm	
Flavor		Imprint Code	S5	
Contains				

l	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:72090-020-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020		



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	06/29/2020	

Labeler - Pioneer Life Sciences, LLC (014092742)

Revised: 7/2020 Pioneer Life Sciences, LLC