

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 are taking 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 HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-020-26	1 in 1 CARTON	06/29/2020	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		

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