

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.

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)	
CROSCARMELOSE 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:72090-020-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2020	

Distributed by: Pioneer Life Sciences • 40E Colliers Ln Suite A, East Brunswick, NJ 08816

Drug Facts

Active Ingredient (in each caplet) Diphenhydramine HCl 25mg

Purpose Night Time 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 such as antihistamines and night-time cough/cold products

Ask your doctor before use if you have: a breathing problem such as asthma, emphysema or chronic bronchitis; glaucoma; trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are:

taking sedatives or tranquilizers or any other sleep-aid

When using this product: drowsiness will occur; avoid alcoholic drinks and other drugs that cause drowsiness; do not drive a motor vehicle or operate 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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as 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 doctor. Children under 12 years of age: do not use. **Other information:** each caplet contains: calcium 23.52mg; store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F). **Read all product information before using.**

WARNING: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, FD&C Blue #1, FD&C Blue #2, lecithin, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyvinyl alcohol, talc, titanium dioxide. **Questions or comments?** Call toll free 1-732-886-8070 Mon to Fri 9am-5pm EST or www.PioneerLifeSciences.com. This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the Registered Trademark Tylenol® Simply Sleep®.



Lot No.

Exp. Dt.

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