

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.

Diphenhydramine HCl 25 mg

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

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 your 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 a doctor or pharmacist before use if you are

- taking sedative or tranquilizers

When using this product

- drowsiness will occur
- avoid alcoholic drinks
- do not drive 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.

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

Distributed by:

Pioneer Life Sciences
40E Cotters Lane, Suite A
East Brunswick, NJ 08816

 <p>†compare to Simply Sleep® active ingredients.</p> <p>GenMed generic medicine</p> <h1>Sleep-Aid</h1> <p>sleep-aid/non habit forming</p> <p>REGULAR STRENGTH DIPHENHYDRAMINE HCl 25mg each caplet</p> <p>NDC 72090-020-25</p> <p>250 caplets not actual size</p>	<h3>Drug Facts</h3> <p>Active Ingredient (in each caplet) Diphenhydramine HCl 25mg..... Sleep-aid</p> <p>Purpose Sleep-aid</p> <p>Uses ■ for relief of occasional sleeplessness</p> <p>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</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers</p> <p>When using this product ■ drowsiness will occur ■ avoid alcoholic drinks ■ do not drive a motor vehicle or operate machinery</p> <p>Stop use and ask a doctor if ■ sleeplessness persist continuously for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.</p>	<h3>Drug Facts (continued)</h3> <p>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</p> <p>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</p> <p>Other information ■ each caplet contains: calcium 15mg ■ store between 20°C-25°C (68°F-77°F); avoid high humidity ■ protect from light ■ read all product information before using</p> <p>Inactive ingredients dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, opadry II</p>	<h3>Drug Facts (continued)</h3> <p>Questions or comments? Call 1-732-698-5070 Monday through Friday 9AM-5PM EST or www.pioneerlifesciences.com</p> <p>†This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark Tylenol® Simply Sleep®.</p> <p>6 80044 64722 17</p> <p>Distributed by: Pioneer Life Sciences 40E Cotters Ln Suite A, East Brunswick, NJ 08816</p> <p>TAMPER EVIDENT Do not use if safety seal under cap is broken or missing.</p> <p>Lot No. _____ Exp. Date _____</p>
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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
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Product Characteristics

Color	blue	Score	no score
Shape	capsule	Size	11mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-020-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	07/31/2018	

Labeler - Pioneer Life Sciences, LLC (014092742)

