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

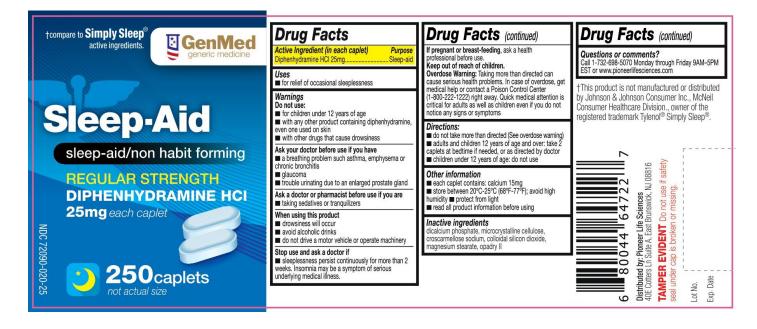
dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, opadry II

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



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

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

l	Packaging				
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	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	