

SLEEPEZE- diphenhydramine hydrochloride tablet
Medtech Products Inc.

SleepEze Caplet 50 mg_Export only 63029-921

Drug Facts

Active ingredient (in each tablet)

Purpose

Diphenhydramine Hydrochloride 50 mg.....Nighttime sleep aid

Uses

● relieves occasional sleeplessness ● helps to reduce difficulty falling asleep

Warnings

Do not use

● if you are elderly, as this drug may cause excitation rather than sedation ● with any other product containing diphenhydramine, even one used on skin ● in children under 12 years of age

Ask a doctor or pharmacist before use if you

● have ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ difficulty urinating ● take sedatives or tranquilizers ● are pregnant or breastfeeding

When using this product

avoid drinking alcohol.

Stop use and ask a doctor if

sleeplessness continues for more than 2 weeks. Sleeplessness may be a symptom of a serious underlying medical illness.

Keep out of reach of children.

In case of overdose, call a poison control centre or get medical help right away.

Directions

Adults and children 12 years and over: ■ take 1 tablet at bedtime if needed, or as directed by a doctor ■ if you feel drowsy in the morning, consult a doctor or pharmacist as you may require a lower dosage (25 mg) ■ do not take more than directed

Other information

■ Store at 20° to 25°C

Inactive ingredients

anhydrous dibasic calcium phosphate, croscarmellose sodium, FD&C blue no. 1 aluminum lake, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, mineral oil, silicon dioxide, stearic acid, talc, titanium dioxide, triacetin, water

SECURITY FEATURE: Safety sealed in individual pouches. Do not use if pouch is not safely sealed.

Important: Keep carton for future reference.

PRINCIPAL DISPLAY PANEL

Sleep.eze
Extra strength
Caplets
10 coated capsules

Relieves Occasional Sleeplessness
Soulagement de l'insomnie occasionelle

Sleep·eze[®] MD

EXTRA STRENGTH

caplets

S Z
Actual Size
Taille réelle

50 mg Diphenhydramine Hydrochloride Tablets
EXTRA FORT
50 mg Chlorhydrate De Diphenhydramine En Comprimés

sleep well tonight... feel alert tomorrow
dormez bien cette nuit...soyez en pleine forme demain

Relieves occasional sleeplessness / Soulagement de l'insomnie occasionelle
Helps to reduce difficulty falling asleep / Aide à réduire la difficulté à s'endormir

10 coated caplets / comprimés-capsules enrobés
safety sealed / indicateur d'effraction

DIN 02229959

SLEEPEZE

diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63029-921
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)	
MINERAL OIL (UNII: T5L8T28FGP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 75EV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	13mm	
Flavor		Imprint Code	S;Z	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-921-10	1 in 1 CARTON	05/23/2012	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63029-921-20	2 in 1 CARTON	05/23/2012	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Export only		05/23/2012		

Labeler - Medtech Products Inc. (122715688)

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Medtech Products Inc.