UNISOM SLEEPMELTS NIGHTTIME SLEEP-AID- diphenhydramine hydrochloride tablet, chewable Chattem, Inc.

Unisom SleepMelts Nighttime Sleep-Aid

Drug Facts

Active ingredient

(in each caplet)

Diphenhydramine HCI 25 mg

Purpose

Nighttime 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

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 a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

avoid alcoholic drinks

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.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years of age and over: 2 tablets (25 mg each) at bedtime if needed, or as directed by a doctor
- place 2 tablets on tongue; tablets dissolve with or without water
- allow tablets to dissolve in mouth or chew before swallowing

Inactive ingredients

citric acid, ethylcellulose, flavor, hydroxypropyl cellulose, mannitol, microcrystalline cellulose, PVP, red 7, starch, sucralose, sucrose (309-154)

Dist. by: CHATTEM, Inc.

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PRINCIPAL DISPLAY PANEL

Unisom® SleepMeltsTM Diphenhydramine HCI tablets, 25 mg NIGHTTIME SLEEP-AID 24 Tablets

UNISOM SLEEPMELTS NIGHTTIME SLEEP-AID

diphenhydramine hydrochloride tablet, chewable

Product Information

 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:41167-0014

 Route of Administration
 ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)
DIPHENHYDRAMINE HYDROCHLORIDE 25 mg

Inactive Ingredients Ingredient Name Strength CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)

HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)

MANNITOL (UNII: 30WL53L36A)

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

POVIDONE (UNII: FZ989GH94E)

D&C RED NO. 7 (UNII: ECW0LZ41X8)

STARCH, CORN (UNII: 08232NY3SJ)

SUCRALOSE (UNII: 96K6UQ3ZD4)

SUCROSE (UNII: C151H8M554)

Product Characteristics

Floudet Characteristics					
Color	pink	Score	no score		
Shape	ROUND	Size	13mm		
Flavor	CHERRY	Imprint Code	U		
Contains					

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41167-0014-0	3 in 1 CARTON	01/01/2008			
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:41167-0014-1	4 in 1 CARTON	01/01/2008			
2		8 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			
OTC Monograph Drug	M010	01/01/2008				

Labeler - Chattem, Inc. (003336013)

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