

DORMIN- diphenhydramine hydrochloride capsule
Randob Labs,Ltd.

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.

Drug Facts

Active ingredient

Diphenhydramine Hydrochloride

Purpose

Keep Out of Reach of Children

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

Uses

- helps to reduce difficulty falling asleep

Warnings

- **Do not use**
- in children under 12 years of age
- with any other product containing diphenhydramine, even one used on skin

Ask Doctor

As a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to enlarged prostate gland

Ask Doctor/Pharmacist

As a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When Using

When using this product

- avoid alcoholic drinks

Stop Use

Stop use and ask a doctor if sleeplessness lasts for more than 2 weeks. Insomnia may be a symptom of serious underlying medical illness.

Pregnancy or Breast Feeding

If pregnant or breast-feeding, ask a health professional before use.

Directions

Adult and children 12 years and over: Take 2 capsules (50 mg) at bedtime if needed or as directed by a doctor

Children under 12 years of age: Do not give this product to children under 12 years of age

Other Information

- keep in dry place

Use by expiration date on pack

Inactive Ingredients

FD&C Red No. 3, Gelatin, Lactose, Magnesium Stearate, Polyethylene Glycol, Silicon Dioxide, Talc.

Principal Display Panel

Dormin®

THE NIGHTTIME SLEEP-AID

With Diphenhydramine Hydrochloride

- FAST
- SAFE
- EFFECTIVE

72 Capsules

Active ingredient (in each capsule)
Diphenhydramine HCl 25 mg. **Purpose:** Nighttime sleep-aid. **Use:** helps to reduce difficulty falling asleep. **Warnings:** Do not use: • in 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 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 lasts 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: take 2 capsules (50 mg) at bedtime if needed or as directed by a doctor. Children under 12 years of age: do not give this product to children under 12 years of age. **Other information:** • keep in dry place • use by expiration date on pack. **Inactive ingredients:** FD&C Red #3, Gelatin, Lactose, Magnesium Stearate, Polyethylene Glycol, Silicon Dioxide, Talc.

ATTENTION: SEALED CAPSULE. DO NOT USE IF RED CAPSULE BAND IS MISSING OR BROKEN. USE ONLY IF PRINTED DORMIN NECKBAND AND PRINTED SEALED FOR YOUR PROTECTION FOIL INNER SEAL ARE INTACT. CHILD RESISTANT SAFETY CAP.

Oct. 1999 **AMDOX** 1033 (Rev. 4/8) Dormin, 10 13213 723 F

DORMIN

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52412-100
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
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4RIU)	

Product Characteristics

Color	PINK (pink cap/pink body with red band)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	Do rmin;25mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52412-100-72	72 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1992	
2	NDC:52412-100-32	32 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/1992	
3	NDC:52412-100-02	2 in 1 POUCH; Type 0: Not a Combination Product	03/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	01/01/1992	

Labeler - Randob Labs, Ltd. (061995007)**Registrant** - Randob Labs, Ltd. (061995007)