DORMMY-LON- diphenhydramine hydrochloride tablet Haendel Farma, S.A. de C.V.

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.

DORMMY-LON

Drug Facts

Active Ingredient (in each pill)

Diphenhydramine hydrochloride 25 mg

Purpose

Nighttime sleep-aid

Uses:

- Helps to reduce difficulty in falling sleep
- For the relief of occasional sleeplessness

Warnings

Ask a doctor before use if you have:

- · A breathing problem such as emphysema or chronic bronchitis
- Glaucoma
- Difficulty in urination due to an enlarged prostate gland

Do not use

- For children under 12 years of age
- With any other product containing diphehydramine

Ask a doctor or pharmacist before use it if you are

taking sedatives, tranquilizers or any other drugs

When using this product

• Avoid alcoholic beverages

Stop use and ask a doctor if

sleeplessness persists continuosly for more than 2 weeks, In sommia 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

• Take only one dose per day (24 hours)

Adults and children 12 years & over	2 pills or as directed by a doctor
children under 12 years	Do not use

Inactive ingredients

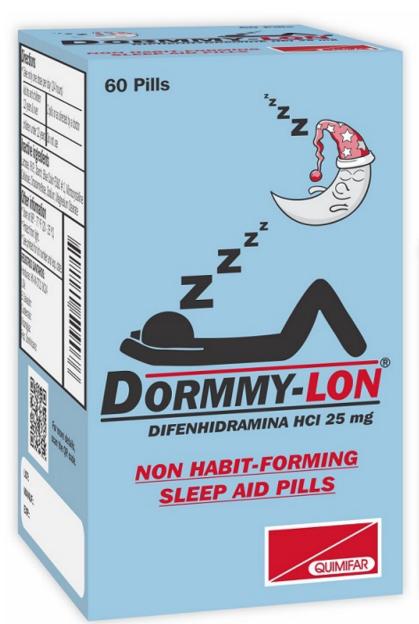
Lactose, P.V.P., Starch, Blue Color FD&C # 1, Microcrystalline Cellulose, Croscarmellose, Sodium, Magnesium Stearate

Other information

- Store at 68° 77 °F (20-25 °C)
- Protect from light.
- See printed for lot number and exp. date.

Package Labeling:







DORMMY-LON

diphenhydramine hydrochloride tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83164-000

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength	
SODIUM (UNII: 9NEZ 333N27)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
CROSCARMELLOSE (UNII: 029TFK992N)		

Product Characteristics				
Color	blue	Score	2 pieces	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	Q	
Contains				

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83164-000- 01	1 in 1 BOX	01/04/2023	
1	L	60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M010	01/04/2023	

Labeler - Haendel Farma, S.A. de C.V. (816368628)

Establishment				
Name	Address	ID/FEI	Business Operations	
Haendel Farma, S.A. de C.V.		816368628	manufacture(83164-000)	

Revised: 1/2023 Haendel Farma, S.A. de C.V.