

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 diphenhydramine*

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 continuously for more than 2 weeks, In somnia 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)*

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

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:

<p>Directions</p> <p>* Take only one dose per day (24 hours)</p> <p>Adults and children 12 years & over: 2 pills or as directed by a doctor</p> <p>Children under 12 years: Do not use</p>	<p>60 Pills</p>  <p>DORMMY-LON DIPHENHYDRAMINE HCl 25 mg</p> <p>NON HABIT-FORMING SLEEP AID PILLS</p> 	<p>Drug Facts</p> <p>Active Ingredient (in each pill) Diphenhydramine hydrochloride 25 mg</p> <p>Purpose Nighttime sleep-aid</p> <p>Uses: * Helps to reduce difficulty in falling asleep * For the relief of occasional sleeplessness</p> <p>Warnings Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> * A breathing problem such as emphysema or chronic bronchitis * Glaucoma * Difficulty in urination due to an enlarged prostate gland <p>Do not use</p> <ul style="list-style-type: none"> * For children under 12 years of age * With any other product containing diphenhydramine <p>Ask a doctor or pharmacist before use if you are taking sedatives, tranquilizers or any other drugs</p> <p>When using this product</p> <ul style="list-style-type: none"> * Avoid alcohol beverages <p>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.</p> <p>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.</p>
<p>Inactive ingredients</p> <p>Lactose, PVP, Starch, Blue Color FD&C # 1, Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate</p> <p>Other information</p> <ul style="list-style-type: none"> * Store at 68° - 77 °F (20 - 25 °C) * Protect from light. * See printed for lot number and exp. date. <p>REGISTROS SANITARIOS</p> <p>Honduras: HA00721-0024</p> <p>USA:</p> <p>El Salvador:</p> <p>Guatemala:</p> <p>Nicaragua:</p> <p>Rep. Dominicana:</p>		

Made in Honduras by LABORATORIO HAENDEL FARMA / QUIMIFAR II
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WHATSAPP: 504 9438-7814

NON HABIT-FORMING SLEEP AID PILLS

DORMMY-LON
DIPHENHYDRAMINE HCl 25 mg



60 Pills



60 Pills



DORMMY-LON
DIFENHIDRAMINA HCl 25 mg

NON HABIT-FORMING SLEEP AID PILLS



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Honduras: HM-M-0721-0024

USA:

El Salvador:


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For more details, scan the QR code.



LOT:
MANUF.:
EXP.:

60 Pills



DORMMY-LON
DIFENHIDRAMINA HCl 25 mg

NON HABIT-FORMING SLEEP AID PILLS



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60 Pills



DORMMY-LON
DIPHENHYDRAMINE HCl 25 mg

NON HABIT-FORMING SLEEP AID PILLS





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 (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM (UNII: 9NEZ333N27)	
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			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83164-000-01	1 in 1 BOX	01/04/2023	
1		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.