SLEEP AID- diphenhydramine hcl capsule, liquid filled
L.N.K. International, Inc.

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.

Quality Plus 44-656

Active ingredient (in each liquid-filled capsule)

Diphenhydramine HCl 50 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
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

avoid alcoholic beverages.

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.

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 (1-800-222-1222) right away.

Directions

- adults and children 12 years of age and over:

1 capsule (50 mg) at bedtime if needed, or as directed by a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- avoid excessive heat
- see end flap for expiration date and lot number

Inactive ingredients

edible white ink, FD&C blue #1, gelatin, glycerin, polyethylene glycol, purified water, sorbitol

Questions or comments?

1-800-426-9391

Principal display panel

QUALITY PLUS NDC 50844-656-19

**Compare to active ingredient in Unisom® SleepGels®*

SLEEP AID

Diphenhydramine HCl 50 mg
NIGHTTIME SLEEP-AID

Non-habit Forming

8
Liquid Gels One Liquid Gel Per Dose ACTUAL SIZE

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Unisom® SleepGels®.
50844 REV0319B65619

Distributed by **LNK INTERNATIONAL, INC.**
60 Arkay Drive
Hauppauge, NY 11788
USA
Product of China
Packaged and Quality Assured in the USA

QUALITY PLUS

SLEEP AID

8 Liquid Gels

NDC 50844-656-19

*Compare to active ingredient in Unisom® SleepGels®

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

No Print / No varnish Area Lot no. & Exp. date

Diphenhydramine HCl 50 mg

NIGHTTIME SLEEP-AID

Non-habit Forming

8 Liquid Gels

One Liquid Gel Per Dose

ACTUAL SIZE

0 50844 29319 9

B-1603-656-19-R
REV0319B65619

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product avoid alcoholic beverages.

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.

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 (1-800-222-1222) right away.

chronic bronchitis
■ difficulty in urination due to enlargement of the prostate gland ■ glaucoma

Questions or comments?

1-800-426-9391

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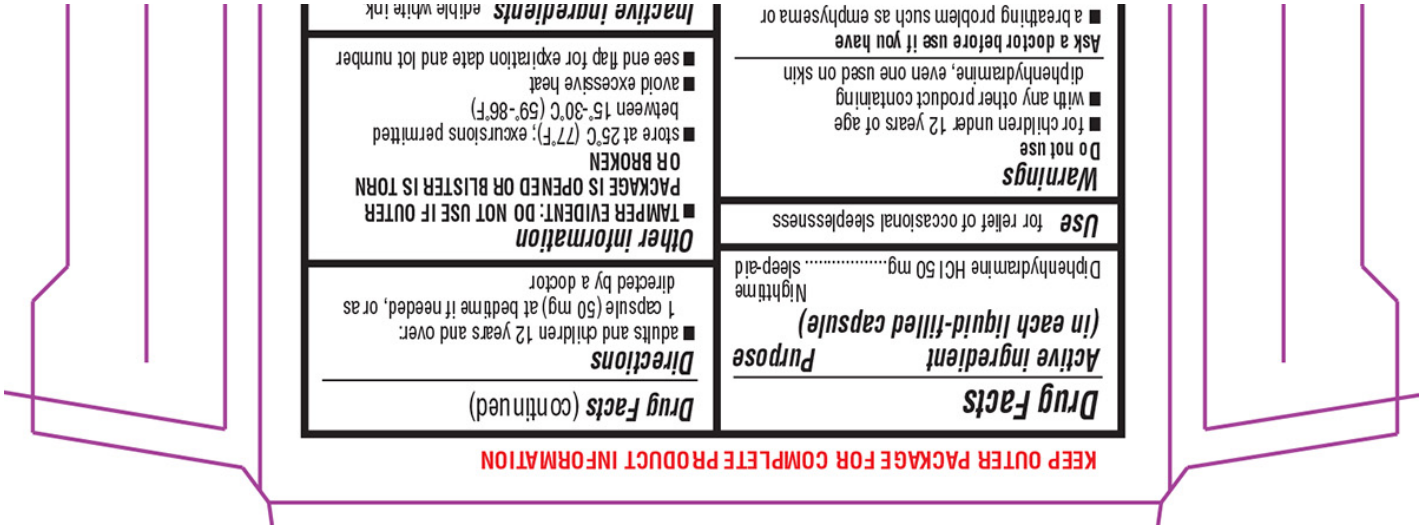

Quality Plus 44-656

SLEEP AID

diphenhydramine hcl capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50844-656
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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	BLUE (light)	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	656
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50844-656-19	1 in 1 CARTON	03/01/2015	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50844-656-27	1 in 1 CARTON	03/01/2015	
2		32 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	part338	03/01/2015	

Labeler - L.N.K. International, Inc. (038154464)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(50844-656)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(50844-656)

Revised: 9/2019 L.N.K. International, Inc.