

**LEADER MAXIMUM STRENGTH SLEEP AID - diphenhydramine hydrochloride capsule,
liquid filled**

Cardinal Health

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.

Leader Nighttime Sleep Aid Maximum Strength

Active Ingredient (in each softgel)

Diphenhydramine HCl 50mg

Purpose

Nighttime sleep aid

Use

helps to reduce difficulty falling asleep

Warnings

Do not give to children under 12 years of age

Do not use this product

with other products containing diphenhydramine, even one used on skin.

Ask a doctor or pharmacist before use if you have

emphysema

chronic bronchitis

glaucoma

difficulty in urination due to an enlargement of the prostate gland

When using this product

avoid alcoholic beverages.

Stop use and ask a doctor if

sleeplessness persists 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 right away.

Directions

adults and children 12 years of age and over: take 1 softgel at bedtime if needed or as directed by a doctor

Other information

- store at controlled room temperature 15°-30°C (59°-86°F)
- 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 Maximum Strength Unisom® SleepGels®.

KEEP OUTER CARTON FOR COMPLETE
WARNINGS AND PRODUCT INFORMATION

edible white ink, FDandC Blue #1, gelatin, glycerin, polyethylene glycol, purified water and sorbitol special.

Questions or comments?

Call toll free: **1-800-200-6313**

Distributed by:
Cardinal Health
Dublin, Ohio 43017

All Leader Brand Products are 100% satisfaction guaranteed or return to place of purchase for a full refund

*Compare to Maximum Strength Unisom® SleepGels®

NDC 37205-0120-64

Maximum Strength Sleep Aid

Diphenhydramine HCl

Helps to reduce difficulty falling asleep

32 softgels

Container Label

NDC 37205-0120-64

LEADER

MAXIMUM STRENGTH

Sleep Aid

Diphenhydramine HCl, 50 mg
NIGHTTIME SLEEP AID

Helps to Reduce Difficulty Falling Asleep

SATISFACTORY GUARANTEE

32 SOFTGELS

Do not use if imprinted safety seal under cap is broken or missing

Drug Facts	Purpose
Active ingredient (in each softgel) Diphenhydramine HCl 50 mg.....Nighttime sleep-aid	
Use ■ helps to reduce difficulty falling asleep	
Warnings KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION. Do not give to children under 12 years of age. Do not use this product with other products containing diphenhydramine, even one used on skin. 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 1 softgel at bedtime if needed or as directed by a doctor	

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017
 CN 3673217
 www.myleader.com
 1-800-200-6313

PLD-A
 LB000048
 Lot No.
 Exp. Date:

All Leader® Brand Products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

Outer Carton Label

Helps to Reduce Difficulty Falling Asleep

NDC 37205-0120-64

LEADER

MAXIMUM STRENGTH

Sleep Aid

Diphenhydramine HCl, 50 mg
NIGHTTIME SLEEP AID

Helps to Reduce Difficulty Falling Asleep

SATISFACTORY GUARANTEE

32 SOFTGELS

Compare to Maximum Strength Unisom SleepAids with 50mg Diphenhydramine

Do not use if imprinted safety seal under cap is broken or missing

Drug Facts	
Active ingredient (in each softgel) Diphenhydramine HCl 50 mg.....	PurposeNighttime sleep-aid
Use ■ helps to reduce difficulty falling asleep	
Warnings Do not give to children under 12 years of age. Do not use this product with other products containing diphenhydramine, even one used on skin. Ask a doctor before use if you have ■ emphysema ■ chronic bronchitis ■ glaucoma ■ difficulty in urination due to an enlargement of the prostate gland Ask a doctor or pharmacist before use if you are now taking sedatives or tranquilizers. When using this product avoid alcoholic beverages. Stop use and ask a doctor if ■ sleeplessness persists 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 right away.	
Directions ■ adults and children 12 years of age and over: take 1 softgel at bedtime if needed or as directed by a doctor	
Other information ■ store at controlled room temperature 15°-30°C (59°-86°F) ■ do not use if imprinted safety seal under cap is broken or missing ■ This product is not manufactured or distributed by Chatham, Inc., owner of the registered trademark Maximum Strength Unisom SleepAids®.	
Inactive ingredients edible white ink, FD&C Blue #1, gelatin, glycerin, polyethylene glycol, purified water and sorbitol special.	

DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017
 CN 3673217
 www.myleader.com
 1-800-200-6313

PLD-A
 FC000028

All Leader® Brand Products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

LEADER MAXIMUM STRENGTH SLEEP AID

diphenhydramine hydrochloride capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-120
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 GLYCOLS (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	blue (BLUE)	Score	no score
Shape	OVAL (OVAL)	Size	13mm
Flavor		Imprint Code	P50;A99
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-120-64	1 in 1 BOX		
1		32 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part338	06/05/2012	

Labeler - Cardinal Health (097537435)