TEXACLEAR NIGHTTIME SLEEP-AID- diphenhydramine hcl liquid GM Pharmaceuticals, 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.

TexaClear Nighttime Sleep-Aid

Active Ingredients

(in each 30 mL)

Diphenhydramine HCl 50 mg

Purpose

Nighttime Sleep-Aid

Uses

- for the relief of occasional sleeplessnes
- reduces time to fall asleep if you have difficulty falling asleep

Warnings

Do not exceed recommended dosage.

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

- breathing problems such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

• taking sedatives or tranquilizers

When using this product

- avoid alcoholic beverages
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

Stop use and ask a doctor if

• sleeplessness persists 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.

Directions

- take only 1 dose per day (24-hour period).
- Do not exceed recommended dosage.
- only use with enclosed dose cup
- mL = mililiter

Adults and children 12 years of age and	30 mL at bedtime if needed or as directed by a
over:	doctor
Children under12 years of age:	Do not use.

Other Information

- each 30 mL contains: Sodium 15 mg
- store at room temperature 20-30°C

Inactive ingredients

citric acid anhydrous, glycerin, proplylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol

Questions or comments?

Call 1-888-535-0305 9 a.m. - 5 p.m. CST.

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

NDC 58809-116-08 TEXACLEAR NIGHTTIME SLEEP-AID 8 fl oz (237mL) TAMPER EVIDENT: DO NOT USE IF FOIL SEAL UNDER CAP IS BROKEN OR MISSING

FAST ACTING FREE & CLEAR **FORMULA**

- Dye Free
- Sugar Free
- Gluten Free
- Alcohol Free
- Acetaminophen Free

Please visit our website www.texaclear.com

Distributed by: GM Pharmaceuticals, Inc. Fort Worth, TX 76118

401113-04 Rev.0723





NIGHTTIME SLEEP-AID

Diphenhydramine HCl 50 mg

For Occasional Sleeplessness or Difficulty Falling Asleep



· Dose: 30 mL before bedtime

Not for treating cold or flu.

LIFT HERE FOR COMPLETE DRUG FACTS





8 fl oz (237 mL)

Drug Facts

Active ingredient (in each 30 mL)

Purpose

Diphenhydramine HCl 50 mg......Nighttime sleep-aid

Uses

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

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

Ask a doctor or pharmacist before use if you are

■ taking sedatives or tranquilizers

When using this product

- avoid alcoholic beverages and other drugs that cause drowsiness
- drowsiness will occur
- do not drive a motor vehicle or operate machinery

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 right away.

Directions

- do not exceed recommended dosage.
- take only one dose per day (24 hours)
- only use with enclosed dose cup
 mL= milliliter

	•
adults and children 12 years of age and over:	30 mL at bedtime if needed or as directed by a doctor.
children under 12 years:	do not use

Other information

- each 30 mL contains: Sodium 15 mg
- store at room temperature 20-30°C (68-86°F)

Inactive ingredients

citric acid anhydrous, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol

Questions or comments?

Call 1-888-535-0305 9 a.m. - 5 p.m. CST.

TEXACLEAR NIGHTTIME SLEEP-AID

diphenhydramine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-116
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 in 30 mL	

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
SORBITOL (UNII: 506T60A25R)			
SACCHARIN SODIUM ANHYDROUS (UNII: 14807BK602)			
WATER (UNII: 059QF0KO0R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:58809-116- 08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2016	

Labeler - GM Pharmaceuticals, Inc. (793000860)

Revised: 8/2023 GM Pharmaceuticals, Inc.