TEXACLEAR KIDS ALLERGY- chlophedianol hcl pyrilamine maleate liquid GM Pharmaceuticals, Inc.

TexaClear Kids Allergy

Active Ingredients

(in each 30 mL (2 TBSP))

Chlophedianol HCl 12.5 mg

Pyrilamine Maleate 25 mg

Purpose

Cough Suppressant

Antihistamine

Uses

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- itchy nose or throat
- sneezing
- itchy, watery eyes
- runny nose
- cough due to minor throat and bronchial irritation

Warnings

Ask doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking, asthma, or emphysema
- glaucoma
- difficulty in urination due to the enlargment of the prostate gland
- cough that occurs with too much phlegm(mucus)
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor or pharmacist before use if you are

taking sedative or tranquilizers

When using this product

- do not use more than directed
- marked drowsiniess may occur
- alcohol, secatives, and tranquilizers may increase drowsiness

- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- Nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days, tend to recur, or are accompanied by a fever, rash or persisten headace. A persisten cough may be a sign of a serious condition.
- new symptoms occur

If pregnant or breast-feeding, as 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 4 doses per 24-hours.
- Use enclosed dose cup and keep with product.
- mL = mililiter

Adults and children 12 years of age and over:	60 mL (2 dose cups) every 6 to 8 hours
Children 6 to under 12 years of age:	30 mL (1 dose cup) every 6 to 8 hours
Children under 6 years of age:	Do not use.

Other Information

- each 30 mL contains: **Sodium 14 mg**
- read all product information before using
- store at room temperature 68-86°F (20-30°C

Inactive ingredients

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

Questions or comments?

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

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

KEEP LEAFLET AFTER OPENING

TexaClear® Kids Allergy + Cough

NDC 58809-925-08 8 fl. oz. (237 mL)

Chlophedianol HCl – Cough Suppressant Pyrilamine Maleate – Antihistamine

Tamper evident: do not use if foil seal under cap is broken on missing

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

Ages 6+

Dose every 6 to 8 hours

- Sneezing
- Runny Nose
- Watery Eyes
- Itchy Nose & Throat
- Cough

Distributed by:

GM Pharmaceuticals, Inc. Fort Worth, TX 76118



Drug Facts

Active ingredients (in each 30 mL)

Purpose

Chlophedianol HCl 12.5 mg......Cough suppressant
Pyrilamine Maleate 25 mg.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- itchy nose or throat sneezing
- itchy, watery eyes
 runny nose
- cough due to minor throat and bronchial irritation

Warnings

Ask a doctor before use if you have

- a cough that lasts or is chronic such as occurs with smoking asthma, or emphysema
- glaucoma
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis

Ask a doctor before use if you are taking sedatives or tranquilizers.

When using this product

- do not use more than directed
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days, tend to recur, or are accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition
- new symptoms occur

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

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children 6 to under 12 years of age:	30 mL (1 dose cup) every 6 to 8 hours		
children under 6 years:	do not use		

Other information

- each 30 mL contains: Sodium 14 mg
- read all product information before using
- store at room temperature 20-30°C (68-86°F)

Inactive ingredients

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

Questions or comments?

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

TEXACLEAR KIDS ALLERGY

chlophedianol hcl pyrilamine maleate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-925
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CHLOPHEDIANOL HYDROCHLORIDE (UNII: 69QQ58998Y) (CHLOPHEDIANOL - UNII:42C50P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	12.5 mg in 30 mL		
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII: HPE317O9TL)	PYRILAMINE MALEATE	25 mg in 30 mL		

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
GLYCERIN (UNII: PDC6A3C0OX)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
SORBITOL (UNII: 506T60A25R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:58809-925- 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 Drug	M12	06/15/2016	

Labeler - GM Pharmaceuticals, Inc. (793000860)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sovereign Pharmaceuticals, LLC		623168267	manufacture(58809-925)	

Revised: 11/2023 GM Pharmaceuticals, Inc.