# TEXACLEAR- allergy relief tablet 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.

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#### TexaClear Fast Acting Allergy Relief Tablet

TEXACLEAR-ALLERGY RELIEF (Chlophedianol HCl, Pyrilamine Maleate) TABLET GM Pharmaceuticals, Inc.

TexaClear Allergy Relief Tablet 30 count Drug Facts

## Active Ingredients (per tablet)

Chlophedianol HCI ..... 25 mg

Pyrilamine Maleate ..... 50 mg

## **Purpose**

Cough Suppressant

**Antihistamine** 

#### Uses

- temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:
  - runny nose
  - itchy, watery eyes
  - itching of the nose or throat
  - sneezing
  - 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
- a cough that occurs with too much phlegm (mucus)
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

#### 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**

• do not exceed 4 tablets per 24-hour period.

adults and children 12 years and older:	take 1 tablet every 6 to 8 hours.
children under 12 years:	do not use.

#### Other Information

- tamper evident: do not use if foil seal under the cap is broken or missing
- This package is child-resistant.
- read all information before using
- store at room temperature 20-30°C (68-86°F)
- avoid excess heat and humidity

## Inactive Ingredients

croscarmellose sodium, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide, stearic acid

#### Questions or comments?

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

#### PRINCIPAL DISPLAY PANEL

NDC 58809-186-30

TEXACLEAR

**ALLERGY** 

RELIEF

30 Tablets



## **TEXACLEAR**

allergy relief tablet

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-186
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLOPHEDIANOL HYDROCHLORIDE (UNII: 69QQ58998Y) (CHLOPHEDIANOL - UNII:42C50P12AP)	CHLOPHEDIANOL HYDROCHLORIDE	25 mg	
<b>PYRILAMINE MALEATE</b> (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	50 mg	

Inactive Ingredients				
Ingredient Name	Strength			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STARCH, CORN (UNII: O8232NY3SJ)				
STEARIC ACID (UNII: 4ELV7Z65AP)				

Product Characteristics				
Color	white	Score	2 pieces	
Shape	OVAL	Size	16mm	
Flavor		Imprint Code	AC	
Contains				

Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-186- 30	30 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/01/2015	

## Labeler - GM Pharmaceuticals, INC (793000860)