

**TEXACLEAR PAIN AND CHEST CONGESTION RELIEF- choline salicylate, guaifenesin liquid**  
**GM Pharmaceuticals, INC**

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**TexaClear Pain & Chest Congestion Relief**

TexaClear Pain & Chest Congestion Relief

(Choline Salicylate, Guaifenesin)

NDC: 58809-218-08

GM Pharmaceuticals, Inc.

**Drug Facts**

**Active ingredients (in each 30 mL)**

Choline Salicylate (NSAID)\* 870 mg

Guaifenesin 200 mg

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever / fever reducer

Expectorant

**Uses**

- temporarily relieves
  - headache
  - sore throat
  - minor aches and pains
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid bronchial passageways of bothersome mucus and make coughs more productive

**Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Salicylates (NSAIDs) may cause a severe allergic reaction which may include:

- hives

- rash
- shock
- skin reddening
- facial swelling
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### **Do not use**

- if you have ever had an allergic reaction to salicylates (including aspirin) or any other pain reliever/ fever reducer.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

#### **Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn or if you have ulcers or bleeding problems
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, diabetes or thyroid disease
- you have a cough with excessive phlegm (mucus)
- you have a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- you are taking a diuretic
- have asthma

#### **Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for anticoagulation (thinning the blood) diabetes, gout, or arthritis.
- under a doctor's care for any serious condition

#### **When using this product do not use more than directed**

#### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days

- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- you experience any of the following signs of stomach bleeding
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use salicylates (NSAID) during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**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.**
- do not take more than 6 doses in any 24-hour period.
- use enclosed dose cup and keep with product
- mL= milliliter

<b>Age</b>	<b>Dose</b>
adults and children 12 years of age and over:	30 mL every 4 hours
children under 12 years of age:	do not use.

**Other information**

- each 30mL contains: **Sodium 17 mg**
- read all product information before using
- store at 68° to 86°F (20° to 30°C)

**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

# PRINCIPAL DISPLAY PANEL

NDC 58809-218-08

TexaClear Pain & Chest Congestion Relief

8 fl oz (237 mL)

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

NDC 58809-218-08

LIFT HERE FOR COMPLETE DRUG FACTS

**FAST ACTING  
FREE & CLEAR  
FORMULA**

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

**TEXACLEAR®**

**PAIN & CHEST  
CONGESTION  
RELIEF**

• Ages: 12+  
• 30 mL every 4 hours

Choline Salicylate 870 mg - Pain Reliever/Fever Reducer (**NSAID**)  
Guaifenesin 200 mg - Expectorant

Headache • Sore Throat  
Thins Mucus • Reduces Fever  
Chest Congestion

**FAST ACTING**

Distributed by:  
GM Pharmaceuticals, Inc.  
Fort Worth, TX 76118  
www.texaclear.com  
401149-01 Rev. 0923

8 fl oz (237 mL)

U.S. Pat: 10,987,365

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## Drug Facts

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## TEXACLEAR PAIN AND CHEST CONGESTION RELIEF

choline salicylate, guaifenesin liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-218
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 30 mL
<b>CHOLINE SALICYLATE</b> (UNII: KD510K1IQW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 30 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-218-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/25/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/25/2023	

**Labeler** - GM Pharmaceuticals, INC (793000860)

Revised: 11/2023

GM Pharmaceuticals, INC