#### 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

Age	Dose
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)



# Drug Facts

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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
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<ul> <li>if you have ever had an allergic reaction to salicylates (including aspirin) or any other pain reliever/fever reducer.</li> <li>if you have ever had an allergic reaction to this product or any of its ingredients</li> <li>in children under 12 years of age</li> </ul>
<ul> <li>Ask a doctor before use if</li> <li>stomach bleeding warning applies to you</li> <li>you have a history of stomach problems, such as heartburn or if you have ulcers or bleeding problems</li> <li>you have high blood pressure, heart disease, liver cirrhosis, kidney disease, diabetes or thyroid disease</li> <li>you have a cough with excessive phlegm (mucus)</li> <li>you have a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema</li> <li>you are taking a diuretic ■ you have asthma</li> </ul>
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#### Drug Facts (continued)

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#### **Questions or comments?**

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## **TEXACLEAR PAIN AND CHEST CONGESTION RELIEF**

choline salicylate, guaifenes in liquid

#### **Product Information**

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58809-218

Route of Administration ORAL

	tive Ingredie	ent/Active Moiety					
		Ingredient Name		Basis of Strength		Strength	
GU	AIFENESIN (UNII	: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)		GUAIFENESIN		00 mg n 30 mL	
	OLINE SALICYLA II:0414PZ4LPZ)	ATE (UNII: KD510K1IQW) (SALICYLIC ACID -		CHOLINE SALICYLATE		70 mg n 30 mL	
In	active Ingre	dients					
		Ingredient Name			Strength		
		<b>DL</b> (UNII: 6DC9Q167V3)					
WATER (UNII: 059QF0KO0R)							
		UNII: 1Q73Q2JULR)					
		M (UNII: SB8ZUX40TY)					
	RBITOL (UNII: 50	· ·					
	YCERIN (UNII: PD	M (UNII: 7FLD91C86K)					
GL							
	ackaging						
Pa	ickagnig						
	Item Code	Package Description	Ma	rketing Start Date	Ma	Date	
#	Item Code NDC:58809- 2	<b>Package Description</b> 37 mL in 1 BOTTLE, PLASTIC; Type 0: Not a ombination Product		-	Ma	rketing End Date	
#	Item Code NDC:58809- 2	37 mL in 1 BOTTLE, PLASTIC; Type 0: Not a		Date	Ma	-	
#	Item Code NDC:58809- 218-08	37 mL in 1 BOTTLE, PLASTIC; Type 0: Not a		Date	Ma	-	
#	Item Code NDC:58809- 218-08	37 mL in 1 BOTTLE, PLASTIC; Type 0: Not a ombination Product	10/2	Date		-	

Labeler -	• GM Pharmaceuticals,	INC (793000860)
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Revised: 10/2024

GM Pharmaceuticals, INC