

TEXACLEAR CONGESTION AND PAIN SINUS RELIEF- choline salicylate, guaifenesin, phenylephrine hydrochloride liquid
GM Pharmaceuticals, INC

TEXACLEAR CONGESTION AND PAIN SINUS RELIEF

TexaClear Congestion and Pain Sinus Relief
(Choline Salicylate, Guaifenesin, Phenylephrine HCl)
NDC: 58809-346-08
GM Pharmaceuticals, Inc.

Drug Facts

Active ingredients (in each 30 mL)

Choline Salicylate (NSAID)* 870 mg

Guaifenesin 200 mg

Phenylephrine HCl 10 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever / fever reducer

Expectorant

Nasal decongestant

Uses

temporarily relieves nasal congestion due to common cold, hay fever and other upper respiratory allergies

- nasal congestion
- minor aches and pains
- headache
- 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 are now taking a prescription monoamine oxidase inhibitor (MAOI)(certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- 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 difficulty in urination due to enlargement of the prostate gland
- you have a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- you have asthma
- you have a sodium restricted diet.

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
- taking a diuretic.

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.
- nervousness, dizziness, or sleeplessness occurs
- 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
- keep dosage cup with product
- mL= milliliter

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 16 mg**
- tamper evident: Do not use if foil seal under cap is broken or missing.
- read all product information before using
- store at 68° to 86°F (20° to 30°C)
- avoid excessive heat and humidity

Inactive ingredients

anhydrous citric acid, 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

Distributed by:

GM Pharmaceuticals, Inc.

Arlington, TX. 76015

KEEP LEAFLET AFTER OPENING

M-R080917

PRINCIPAL DISPLAY PANEL

NDC 58809-346-08

TEXACLEAR

Congestion & Sinus Pain Relief

8 fl oz(237 mL)

**FAST ACTING
FREE & CLEAR
FORMULA**

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

NDC 58809-346-08

TEXACLEAR

CONGESTION & SINUS PAIN RELIEF

Choline Salicylate - Pain Reliever / Fever Reducer (NSAID)
Guaifenesin - Expectorant
Phenylephrine HCl - Nasal Decongestant

Sinus Pressure • Headache
Chest & Nasal Congestion
Thins Mucus

FAST ACTING

patent pending

8 fl oz (237 mL)

5 88809 34608 8

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

LIFT HERE FOR COMPLETE DRUG FACTS

• Ages: 12+
• 30 mL every 4 hours

Please visit our website www.texaclear.com

Distributed by:
GM Pharmaceuticals, Inc.
Arlington, TX 76015

Drug Facts

Active ingredients (in each 30 mL)	Purpose
Choline Salicylate (NSAID) ¹ 870 mg	Pain reliever/fever reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

¹nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves
 - nasal congestion
 - headache
 - minor aches and pains
 - sinus congestion and pressure
- 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 (whooshing)

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

Some 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 are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- 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 disease, kidney disease, diabetes or thyroid disease
- you have difficulty in urination due to enlargement of the prostate gland
- you have a cough with excessive phlegm (mucus)

Drug Facts (continued)

- you have a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- you are taking a diuretic
- you 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
- taking a diuretic.

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.
- nervousness, dizziness, or sleeplessness occurs
- 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
- 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 30 mL contains: Sodium 16 mg
- read all product information before using
- store at 20° to 30°C (68° to 86°F)

Inactive ingredients

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

Questions or comments?

Call 1-888-535-4305 9 a.m. - 5 p.m. CST

062518

TEXACLEAR CONGESTION AND PAIN SINUS RELIEF

choline salicylate, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-346
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 30 mL
CHOLINE SALICYLATE (UNII: KD510K1IQW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

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

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-346-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/21/2014	09/30/2024

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/21/2014	09/30/2024

Labeler - GM Pharmaceuticals, INC (793000860)

Revised: 11/2023

GM Pharmaceuticals, INC