

**TEXACLEAR NIGHT TIME COUGH COLD/FLU- choline salicylate,  
diphenhydramine hydrochloride, phenylephrine hydrochloride liquid  
GM Pharmaceuticals, INC**

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**TEXACLEAR NIGHT TIME COUGH COLD FLU**

TEXACLEAR NIGHT TIME COUGH COLD/FLU- (choline salicylate, diphenhydramine hydrochloride, phenylephrine hydrochloride) liquid

GM Pharmaceuticals, Inc.

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TEXACLEAR NIGHT TIME COUGH COLD/FLU

**Drug Facts**

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

Choline Salicylate (NSAID)\* 870 mg

Diphenhydramine HCl 50 mg

Phenylephrine HCl 10 mg

\*nonsteroidal anti-inflammatory drug

**Purpose**

Pain reliever / fever reducer

Antihistamine

Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- minor aches and pains
- runny nose
- sneezing
- watery eyes
- sore throat
- headache
- temporarily reduces fever

**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 warnings**

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**

- in children under 12 years of age
- if you have ever had an allergic reaction to salicylates (including aspirin) or any other pain reliever/fever reducer
- with any other drug containing diphenhydramine, even one used on the skin
- 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

### **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, thyroid disease, or glaucoma
- you have difficulty in urination due to enlargement of the prostate gland
- you have a breathing problem such as emphysema or chronic bronchitis
- 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

### **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 sedatives or tranquilizers
- taking a diuretic

### **When using this product**

- do not use more than directed
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, 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**

- 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 (NSAIDs) 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 15 mg
- store at 20° to 30°C (68° to 86°F)
- this package is child-resistant
- read all product information before using

**Inactive ingredients**

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

**PRINCIPAL DISPLAY PANEL**

NDC 58809-372-08

TEXACLEAR NIGHTTIME COLD & FLU RELIEF

8 fl oz (237 mL)

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

NDC 58809-372-08

**TEXACLEAR**

**NIGHTTIME COLD & FLU RELIEF**

FAST ACTING  
FREE & CLEAR  
FORMULA

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

Choline Salicylate - Pain Reliever/Fever Reducer (NSAID)  
Diphenhydramine HCl - Antihistamine  
Phenylephrine HCl - Nasal Decongestant

Aches • Fever • Sore Throat  
Nasal Congestion • Watery Eyes  
Runny Nose • Sneezing

• Ages: 12+  
• 30 mL every 4 hours  
• Children under 12: Do not use

Please visit our website  
[www.texaclear.com](http://www.texaclear.com)

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

8 fl oz (237 mL)

U.S. Pat. 10,987,365

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choline salicylate, diphenhydramine hydrochloride, phenylephrine hydrochloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58809-372
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHOLINE SALICYLATE</b> (UNII: KD510K1IQW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 30 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-372-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/23/2014	10/31/2024



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/23/2014	10/31/2024

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

Revised: 11/2023

GM Pharmaceuticals, INC