

TEXACLEAR DAYTIME COUGH COLD/FLU- choline salicylate, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid
GM Pharmaceuticals, INC

TEXACLEAR DAYTIME COUGH COLD FLU

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GM Pharmaceuticals, Inc.

TEXACLEAR DAYTIME COUGH COLD/FLU

Drug Facts

Active ingredients (in each 30 mL)

Choline Salicylate (NSAID)* 870 mg

Dextromethorphan HBr 20 mg

Guaifenesin 200 mg

Phenylephrine HCl 10 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever / fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

temporarily relieves these common cold and flu symptoms:

- Cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the 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 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.
- 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, or thyroid disease
- you have chronic pulmonary disease or shortness of breath
- you have difficulty in urination due to enlargement of the prostate gland
- 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 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 (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 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 30mL contains: **Sodium 15 mg**

- read all product information before using
- store at 20° to 30°C (68° to 86°F)

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. – 5p.m. CST

PRINCIPAL DISPLAY PANEL

NDC 58809-391-08

TEXACLEAR DAYTIME COUGH COLD & FLU

8 fl oz (237)

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

NDC 58809-391-08

LIFT HERE FOR COMPLETE DRUG FACTS

**FAST ACTING
FREE & CLEAR
FORMULA**

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

TEXACLEAR

**DAYTIME
COUGH COLD
& FLU RELIEF**

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

- Ages: 12+
- 30 mL every 4 hours

**Aches • Fever • Sore Throat
Nasal & Chest Congestion
Thins Mucus • Cough**



Please visit our website
www.texaclear.com

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

8 fl oz (237 mL)

U.S. Pat: 10,987,365



Drug Facts

Active Ingredients (In each 30 mL) **Purpose**
Choline Salicylate (NSAID) 870 mg.....Pain reliever/fever reducer
Dexamethasone HCl 20 mg.....Cough Suppressant
Phenylephrine HCl 10 mg.....Nasal decongestant
Nonoxonyl anti-inflammatory drug

Uses

- temporarily relieves these common cold and flu symptoms:
 - cough
 - nasal congestion
 - headache
 - sore throat
 - minor aches and pains
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageway of bothersome mucus and make coughs more productive.

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chickenpox 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 redness
- 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).

Do not take more than 3 or more alcoholic drinks every day while using this product. Some warning signs of liver damage persist for more than 2 days, is accompanied by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not take

- if you are under 12 years of age
- if you are taking any other 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

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 chronic pulmonary disease or shortness of breath
- you have difficulty in urination due to enlargement of the prostate gland
- 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

<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> ■ 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 <p>When using this product, do not use more than directed</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ 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 ■ rashness 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: <ul style="list-style-type: none"> ■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better <p>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.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	<p>Directions</p> <ul style="list-style-type: none"> ■ 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 <p>adults and children 12 years of age and over: 30 mL every 4 hours do not use children under 12 years of age: do not use</p>
<p>Other information</p> <ul style="list-style-type: none"> ■ each 30mL contains Sodium 15 mg ■ read all product information before using ■ store at 20° to 30°C (68° to 86°F) 	<p>Inactive ingredients</p> <p>citric acid, dextrose, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol</p>
<p>Questions or comments?</p> <p>Call 1-888-335-0805 9 a.m. - 5 p.m. CST</p>	

P-XX100904-V2

choline salicylate, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-391
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHOLINE SALICYLATE (UNII: KD510K1IQW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 30 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-391-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/21/2014	08/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/21/2014	08/31/2024

Labeler - GM Pharmaceuticals, INC (793000860)

Establishment

Name	Address	ID/FEI	Business Operations
MONARCH PCM LLC		080000294	manufacture(58809-391)

Revised: 11/2023

GM Pharmaceuticals, INC