

**TEXACLEAR PAIN RELIEVER- caffeine, choline salicylate liquid
GM Pharmaceuticals, INC**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

TEXACLEAR PAIN RELIEVER 8 oz

TEXACLEARPain Reliever

(choline salicylate&caffeine), solution

GM Pharmaceuticals, Inc.

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TexaClearPain Reliever Drug Facts

Drug Facts

Active Ingredients per 30mL

Caffeine 65 mg

Choline Salicylate (NSAID)* 870 mg

Purpose

Pain Reliever Aid

Pain Reliever / Fever Reducer (**NSAID**)

*nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - minor arthritis pain
 - muscle aches
 - menstrual cramps
 - backache
- 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
- skin reddening
- rash
- facial swelling
- shock
- 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 blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription 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

Do not use

- if you ever had an allergic reaction to salicylates (including aspirin) or any other pain reliever/ fever reducer.

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have a history of stomach problems such as heartburn, upset stomach, stomach pain, or ulcers
- you have asthma

Ask a doctor or pharmacist before use if

- under a doctor's care for any serious condition
- taking a prescription drug for diabetes, gout, or arthritis.

When using this product

- limit the use of caffeine-containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat
- the recommended dose of this product contains about as much caffeine as a cup of coffee

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- 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
- symptoms do not improve
- pain gets worse or lasts more than 10 days
- ringing in the ears or loss of hearing occurs
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days

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 take more than directed.**
- adults and children 12 years of age and over: take 30mL every 6 hours, while symptoms persist
- do not take exceed 4 doses in any 24 hours unless directed by a doctor
- children under 12 years of age: ask a doctor
- use enclosed dose cup

Other Information

- each 30mL contains: **Sodium 19 mg**
- read all product information before using
- store at room temperature 68-86°F (20-30°C)
- avoid excessive heat and humidity
- tamper evident: Do not use if foil seal under cap is broken or missing read all

Inactive Ingredients

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

Questions or comments?

Call 1-888-423-0139

R071316M

PRINCIPAL DISPLAY PANEL

NDC 58809-389-08

TEXACLEAR

Pain

Reliever

8 fl oz (237 mL)

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

NDC 58809-389-08

TEXACLEAR

FAST-ACTING PAIN RELIEF LIQUID

FAST ACTING FREE & CLEAR FORMULA

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

Caffeine 65 mg- Pain Reliever Aid
Choline Salicylate 870 mg- Pain Reliever/Fever Reducer (NSAID)

Headache • Menstrual Cramps
Backache • Muscle Aches
Minor Arthritis Pain

FAST ACTING

• Ages: 12+
• 30 mL every 6 hours

LIFT HERE FOR COMPLETE DRUG FACTS

Distributed by:
GM Pharmaceuticals, Inc.
Fort Worth, TX 76118
www.texaclear.com
401071-01 Rev. 0623

8 fl oz (237 mL)

U.S. Pat: 10,987,365

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Drug Facts

Active ingredients (in each 30 mL)

Caffeine 65 mg.....	Pain reliever aid
Choline Salicylate (NSAID)* 870 mg.....	Pain reliever/fever reduce
*nonsteroidal anti-inflammatory drug	

Purpose

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - minor arthritis pain
 - muscular aches
- backache
- menstrual cramps
- 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 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**
- 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.

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have a history of stomach problems, such as heartburn, upset stomach, stomach pain or ulcers
- 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

Drug Facts (Continued)

When using this product limit the use of caffeine-containing drugs, foods, or drinks because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat. The recommended dose of this product contains about as much caffeine as a cup of coffee.

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- 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
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- symptoms do not improve
- ringing in the ears or a loss of hearing occurs

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 4 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 6 hours, while symptoms persist
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. - 5 p.m. CST

TEXACLEAR PAIN RELIEVER

caffeine, choline salicylate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-389
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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CHOLINE SALICYLATE (UNII: KD510K1IQW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 30 mL
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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:58809-389-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/14/2017	

Labeler - GM Pharmaceuticals, INC (793000860)

Establishment

Name	Address	ID/FEI	Business Operations
Sovereign Pharmaceuticals, LLC		623168267	manufacture(58809-389)

Revised: 8/2023

GM Pharmaceuticals, INC