

CODEINE-GUAIFENESIN- codeine phosphate and guaifenesin solution
Westminster Pharmaceuticals, LLC

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.

Codeine-Guaifenesin

Drug Facts

Active ingredients (in each 5 mL = 1 tsp)	Purpose
Codeine phosphate, USP 10 mg	Antitussive
Guaifenesin, USP 100 mg	Expectorant

Uses

- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
 - your cough to help you sleep
 - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Ask your doctor before use if

- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

When using this product

- giving a higher dose than recommended by a doctor could result in serious side effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age.
- may cause or aggravate constipation

Stop use and ask a doctor if

- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not exceed 6 doses in 24 hours.

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
---	--

Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Other information

Store at controlled room temperature 15°-30°C (59°-86°F).

You may report side effects by calling 1-844-221-7294 or FDA at 1-800-FDA-1088.

Inactive ingredients

Cherry Flavor, Citric Acid Anhydrous, Glycerin, Masking Agent, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sorbitol Solution, Sucralose.

PRINCIPAL DISPLAY PANEL - 118 mL Bottle Label

NDC 69367-272-04

Codeine-Guaifenesin

Oral Solution

10-100 mg/5 mL

Antitussive/Expectorant

Sugar Free, Alcohol Free, Dye Free

Each 5 mL (1 teaspoonful) contains:

Codeine phosphate, USP

10 mg

Guaifenesin, USP

100 mg

(WARNING: May be habit-forming)

4 fl. oz. (118 mL)

Westminster

Pharmaceuticals

NDC 69367-272-04

Codeine-Guaifenesin Oral Solution

10-100 mg/5 mL

Antitussive/Expectorant

Sugar Free, Alcohol Free, Dye Free

Each 5 mL (1 teaspoonful) contains:
Codeine phosphate, USP..... 10 mg
Guaifenesin, USP..... 100 mg
(WARNING: May be habit-forming)

4 fl. oz. (118 mL)

WP Westminster
Pharmaceuticals

Tamper evident by foil seal under cap.
Do not use if foil seal is broken or missing.



Drug Facts (continued)

Other information

Store at controlled room temperature 15°-30°C (59°-86°F).
You may report side effects by calling 1-844-221-7294 or
FDA at 1-800-FDA-1088.

Inactive ingredients

Cherry Flavor, Citric Acid Anhydrous, Glycerin, Masking Agent, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate, Sorbitol Solution, Sucralose.

Manufactured for:

Westminster Pharmaceuticals, LLC
Nashville, TN 37217

Rev. 07/20

Drug Facts (continued)

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

do not exceed 6 doses in 24 hours.

Adults and children 12 years of age and over:	2 tsp (10 mL) every 4 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 tsp (5 mL) every 4 hours, or as directed by a doctor.
Children under 6 years of age:	Consult a doctor.

Drug Facts

Active ingredients (in each 5 mL = 1 tsp)	Purpose
Codeine phosphate, USP 10 mg	Antitussive
Guaifenesin, USP 100 mg	Expectorant

Uses temporarily relieves:
cough due to minor throat and bronchial irritation as may occur with a cold or inhaled irritants
your cough to help you sleep

Lift Here

Drug Facts (continued)

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Ask your doctor before use if

- you have a persistent cough, this may be a sign of a serious condition
- you have a persistent cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- you have a cough that is accompanied by excessive phlegm (mucus)
- you have chronic pulmonary disease or shortness of breath
- giving to a child who is taking other drugs

When using this product

- giving a higher dose than recommended by a doctor could result in serious side effects for your child. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age.
- may cause or aggravate constipation

Stop use and ask a doctor if

- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash or persistent headache. These may be symptoms of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

CODEINE-GUAIFENESIN

codeine phosphate and guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69367-272
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Codeine Phosphate (UNII: GSL05Y1MN6) (Codeine Anhydrous - UNII:UX6OWY2V7J)	Codeine Phosphate	10 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 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, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-272-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	
2	NDC:69367-272-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/15/2020	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 7/2020

Westminster Pharmaceuticals, LLC