

CODEINE-GUAIFENESIN- codeine phosphate and guaifenesin solution
Method 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 Oral Solution

Active ingredient

(in each teaspoonful (5 mL))

Codeine Phosphate USP 10 mg

Purpose

Antitussive

Active ingredient

(in each teaspoonful (5 mL))

Guaifenesin USP 100 mg

Purpose

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 makes cough 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 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).

Inactive ingredients

Cherry Flavor, Citric Acid, Glycerin, Masking flavor, Propylene glycol, Purified Water, Sodium Citrate, Sodium Benzoate, Sucralose Sorbitol.

Principal Display Panel

NDC 58657-500-16

Codeine-Guaifenesin Oral Solution

10-100 mg/5 mL

Antitussive

Expectorant

16 fl. oz. (473 mL)

Drug Facts
Active ingredients (in each teaspoonful (5 mL))
 Codeine Phosphate USP 10 mg
 Guaifenesin USP 100 mg
Purpose
 Antitussive 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 both excessive mucus and makes cough more productive.

Contraindication Codeine should not be used to treat pain or cough in children younger than 12 years.

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.

Breastfeeding is not recommended when taking codeine due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Method Pharmaceuticals
 NDC 58657-500-16
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

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.
16 fl. oz. (473 mL)

Drug Facts (continued)
 Adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease should not use codeine as it may increase the risk of serious breathing problems.
If pregnant or breastfeeding, 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).

Inactive ingredients
 Cherry Flavor, Citric Acid, Glycerin, Masking Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Benzoate, Sucralose, Sorbitol

Questions?
 1-877-251-3427 M-F (8 a.m. to 5 p.m.CST), or directly to Medwatch at 1-800-332-1888. Serious side effects associated with use of this product may be reported to this number.

Manufactured For:
 Method Pharmaceuticals, LLC
 Fort Worth, TX 76118
 Rev. 6/13

Lot:
 Exp.:

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CODEINE-GUAIFENESIN

codeine phosphate and guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58657-500
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 CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-500-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2014	
2	NDC:58657-500-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2014	

Labeler - Method Pharmaceuticals, LLC (060216698)**Establishment**

Name	Address	ID/FEI	Business Operations
Monarch PCM, LLC		080000294	manufacture(58657-500)

Revised: 12/2021

Method Pharmaceuticals, LLC