**CODEINE-GUAIFENESIN- codeine phosphate and guaifenesin solution**
**Method Pharmaceuticals, LLC**

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**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)


# 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** | CIII |

| 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 Drug | M012 | 04/01/2014 | |

## Labeler - Method Pharmaceuticals, LLC (060216698)

Revised: 10/2025 Method Pharmaceuticals, LLC