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

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**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, methylparaben, potassium citrate, potassium sorbate, propylparaben, propylene glycol, purified water, sorbitol, sucralose.

**PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label**

NDC 69367-272-16

Codeine-
Guaifenesin
Oral Solution
10-100 mg/5 mL

Antitussive/Expectorant

Sugar Free, Alcohol Free, Dye Free

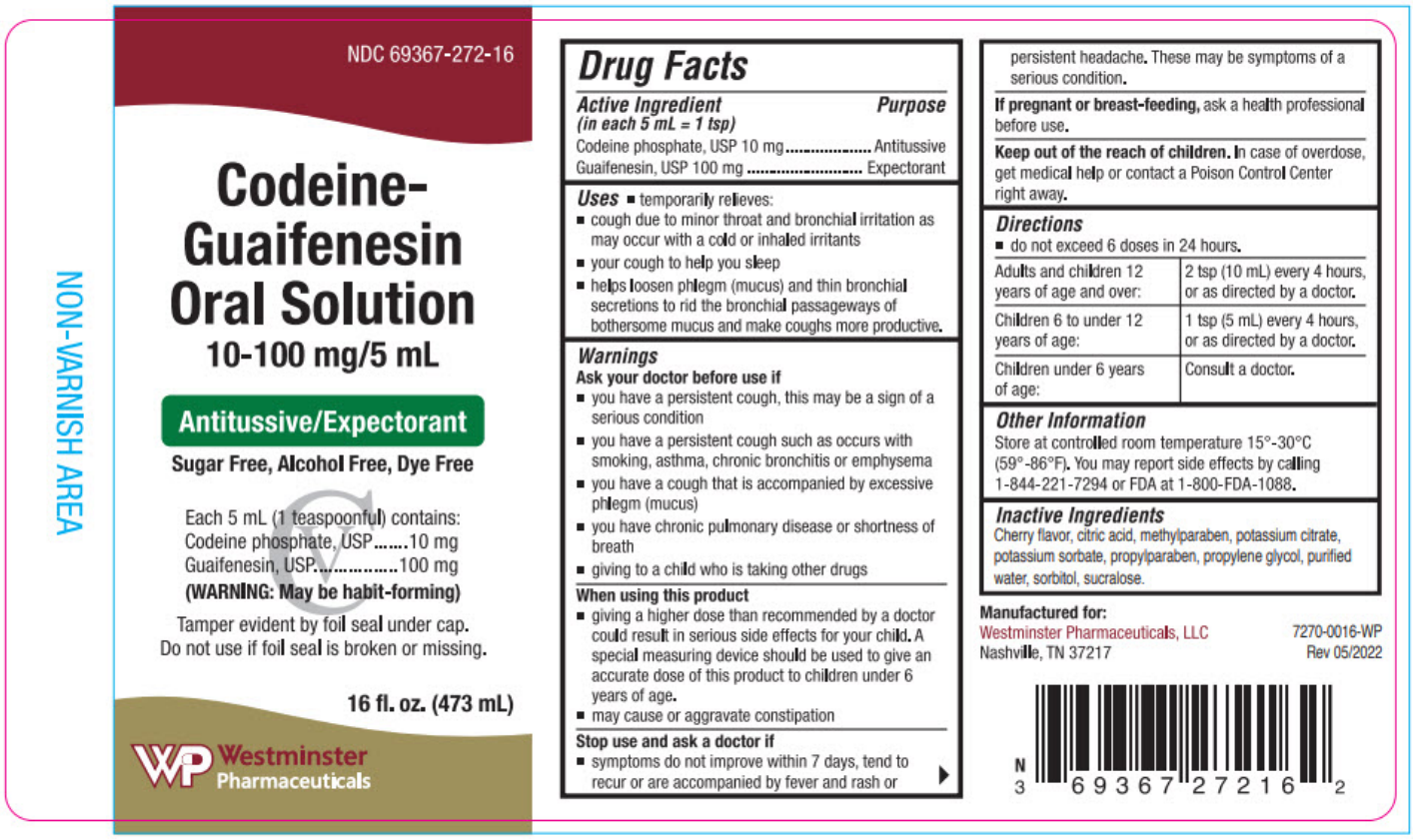
Each 5 mL (1 teaspoonful) contains:
Codeine phosphate, USP
10 mg
Guaifenesin, USP
100 mg

(WARNING: May be habit-forming)

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

16 fl. oz. (473 mL)

Westminster
Pharmaceuticals




# 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) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **POTASSIUM CITRATE** (UNII: EE90ONI6FF) | |
| **POTASSIUM SORBATE** (UNII: 1VPU26JZZ4) | |

| | |
|---|---|
| **SORBITOL** (UNII: 506T60A25R) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |

| 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 DRUG | M012 | 07/15/2020 | |

## Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 7/2020 Westminster Pharmaceuticals, LLC