GUAIFENESIN- guaifenesin liquid Method Pharmaceuticals, LLC

Guaifenesin NDC 58657-508-16 Guaifenesin Liquid USP 100 mg/5 Ml Expectorant Sugar Free • Alcohol Free Cherry Flavor Loosens and Relieves Chest Congestion 16 fl. oz. (473 mL) Drug Facts

Active ingredient (in each 5 mL)

Guaifenesin 100 mg

Purpose

Expectorant

Uses

 helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

When using this product

• Do not use more than directed

Stop use and ask a doctor if

 cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs 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 take more than 6 doses in any 24-hour period

| age | dose |
|---------------------------------------|------------------------------------|
| adults and children 12 years and over | 2 to 4 teaspoonfuls every 4 hours |
| children 6 years to under 12 years | 1 to 2 teaspoonfuls every 4 hours |
| children 2 to under 6 yars | 1/2 to 1 teaspoonful every 4 hours |
| children under 2 years | ask a doctor |

Other information

- store at 20°-25°C (68°-77°F)
- packaged with tamper evident seal under cap
- each 5 mL contains: sodium 3 mg

Inactive ingredients

Caramel, citric acid anhydrous, dextrose, FD&C red #40, flavor, gylcerin, high fructose corn syrup, menthol, purified water, saccharin, sodium, sodium benzoate

Questions or Comments

1-877-250-3427

Manufactured For: Method Pharmaceuticals, LLC Southlake, TX 79092

LR-205

Rev-2024

PRINCIPAL DISPLAY PANEL

NDC 58657- 508- 16

Guaifenesin

Liquid USP

100 mg/ 5 mL

Expectorant

16 fl. oz. (473 mL)

| Drug Facts | Pharmaceuticals | Drug Facts (continued) | dose |
|--|---|--|---|
| Active ingredient (in each 5 mL or 1 teaspoontul) Purpose Guaifenesin, USP 100 mg | NDC 58657-508-16 | adults and children 12 years and over | 2 to 4 teaspoonfuls every 4 hours |
| Uses helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive. | Guaifenesin | children 6 years to under 12 years children 2 years to under 6 years | 1 to 2 teaspoonfuls every 4 hours ½ to 1 teaspoonful every 4 hours |
| Warnings Ask a doctor before use if you have = cough that occurs with too much phlegm (mucus) = cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema | Oral Solution USP | children under 2 years Other information = store at 20°-25°C (68°-77°F) = packaged with tamper evident sx = each 5 mL contains: sodium 3 r | ask a doctor eal under cap |
| When using this product Do not use more than directed | Too ing/o inc | Inactive ingredients | |
| Stop use and ask a doctor if ■ cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition. | Expectorant | Caramel, citric acid anhydrous, dey glycerin, high fructose corn syrup, sodium, sodium benzoate Questions or Comments | menthol, purified water, sacchari |
| 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. | Cherry Flavor Loosens and Relieves Chest Congestion | 1-877-250-3427 Manufactured For: Method Pharmaceuticals, LLC Southlake, TX 76092 | LR-20 Rev 02/202 |
| Directions • do not take more than 6 doses in any 24-hour period | DO NOT USE IF TAMPER EVIDENT SEAL UNDER CAP IS BROKEN OR MISSING | 3 5865 | 67-50816 6 |

| guaifenesin liquid | | | | | |
|--|---|-----------|----------|---------|----------------------|
| Product Information | | | | | |
| Product mormation | | | | | |
| Product Type | HUMAN OTC DRUG | Item Code | (Source) | NDC:586 | 57-508 |
| Route of Administration | ORAL | | | | |
| | | | | | |
| | | | | | |
| Active Ingredient/Active | Moiety | | | | |
| Ingredient Name Basis of Strengt | | | | | trength |
| GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) GUAIFENESIN | | | | | |
| GUAIFENESIN (UNII: 495W7451V0 |)) (GUAIFENESIN - UNII:495W | /7451VQ) | - | 100 | mg in 5 ml |
| GUAIFENESIN (UNII: 495W7451V0 |)) (GUAIFENESIN - UNII:495W | /7451VQ) | - | 100 | mg in 5 ml |
| |)) (GUAIFENESIN - UNII:495W | 77451VQ) | - | 100 | mg in 5 ml |
| GUAIFENESIN (UNII: 495W7451V0 | ?) (GUAIFENESIN - UNII:495W | /7451VQ) | - | 100 | mg in 5 ml |
| | (GUAIFENESIN - UNII:495W) Ingredient Name | /7451VQ) | - | | mg in 5 ml rength |
| | | /7451VQ) | - | | |
| Inactive Ingredients | | /7451VQ) | - | | |
| Inactive Ingredients MENTHOL (UNII: L7T10EIP3A) | | /7451VQ) | - | | |
| Inactive Ingredients MENTHOL (UNII: L7T10EIP3A) CARAMEL (UNII: T9D99G2B1R) | Ingredient Name | /7451VQ) | - | | |
| Inactive Ingredients MENTHOL (UNII: L7T10EIP3A) CARAMEL (UNII: T9D99G2B1R) DEXTROSE (UNII: IY9XDZ35W2) | Ingredient Name XF417D3PSL) | /7451VQ) | - | | |
| Inactive Ingredients MENTHOL (UNII: L7T10EIP3A) CARAMEL (UNII: T9D99G2B1R) DEXTROSE (UNII: IY9XDZ35W2) ANHYDROUS CITRIC ACID (UNII: | Ingredient Name XF417D3PSL) | /7451VQ) | - | | |
| Inactive Ingredients MENTHOL (UNII: L7T10EIP3A) CARAMEL (UNII: T9D99G2B1R) DEXTROSE (UNII: IY9XDZ35W2) ANHYDROUS CITRIC ACID (UNII: FD&C RED NO. 40 (UNII: WZB91 | Ingredient Name XF417D3PSL) | /7451VQ) | - | | |
| Inactive Ingredients MENTHOL (UNII: L7T10EIP3A) CARAMEL (UNII: T9D99G2B1R) DEXTROSE (UNII: T9D9G2B1R) DEXTROSE (UNII: IY9XDZ35W2) ANHYDROUS CITRIC ACID (UNII: FD&C RED NO. 40 (UNII: WZB91 GLYCERIN (UNII: PDC6A3C0OX) | Ingredient Name XF417D3PSL) 27XOA) | /7451VQ) | - | | |

| HI | GH FRUCTOSE CO | RN SYRUP (| UNII: XY6UN3QB6S) | | | | |
|-----------------------|------------------------------|-----------------------|--------------------------------|-------------------------|-------------------------|-------------------|-----|
| | | | | | | | |
| Pı | roduct Charac | teristics | | | | | |
| Co | olor | | red | Score | | | |
| Sh | ape | | | Size | | | |
| Fla | avor | | CHERRY | Imprint G | Code | | |
| Co | ontains | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # | ltem Code | Package Description | | Marketing Start Date | Marketing Date | End | |
| 1 | | 73 mL in 1 B oduct | OTTLE; Type 0: Not a Cor | nbination | 04/01/2024 | | |
| | | | | | | | |
| Marketing Information | | | | | | | |
| | Marketing | Applica | tion Number or Mon Citation | ograph | Marketing Start Date | Marketing Date | End |
| | Category | | | | | | |
| от | Category C Monograph Drug | M012 | | | 04/01/2024 | | |

Labeler - Method Pharmaceuticals, LLC (060216698)

Revised: 4/2024

Method Pharmaceuticals, LLC