**RITUSSIN DM- dextromethorphan hydrobromide and guaifenesin liquid**
**Rij Pharmaceutical Corporation**

*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.*

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**Drug Facts**

**Active ingredients (in each 5 mL)(one teaspoonful)**

Dextromethorphan HBr, USP 10 mg

Guaifenesin, USP 100 mg

**Purpose**

Cough suppressant

Expectorant

**Use**

temporarily relieves cough due to minor throat and bronchial irritation as may occur with cold

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

**Warnings**

**Do not use**

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**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

**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 of age and over | 2 teaspoonfuls every 4 hours |

| | |
|---|---|
| children 6 years to under 12 years of age | 1 teaspoonful every 4 hours |
| children 2 years to under 6 years of age | 1/2 teaspoonful every 4 hours |
| under 2 years of age | ask a doctor |

**Other information**

- store at room temperature 15º - 30°C (59º - 86°F)
- protect from freezing.
- protect from light.
- Each teaspoon (5 mL) contains: sodium 2 mg.
- **TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING**

**Inactive ingredients**

citric acid, FD&C Red #40, flavors, glucose, glycerin, high fructose corn syrup, menthol, saccharin sodium, sodium benzoate, water

**PRINCIPAL DISPLAY PANEL**


# RITUSSIN DM

dextromethorphan hydrobromide and guaifenesin liquid

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:53807-409 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) | DEXTROMETHORPHAN | 10 mg |

| | | |
|---|---|---|
| (DEXTROMETHORPHAN - UNII:7355X3ROTS) | HYDROBROMIDE | in 5 mL |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 100 mg in 5 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL) | |
| **DEXTROSE** (UNII: IY9XDZ35W2) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **HIGH FRUCTOSE CORN SYRUP** (UNII: XY6UN3QB6S) | |
| **MENTHOL** (UNII: L7T10EIP3A) | |
| **SACCHARIN SODIUM** (UNII: SB8ZUX40TY) | |
| **SODIUM BENZOATE** (UNII: OJ245FE5EU) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | RED | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | CHERRY | **Imprint Code** | |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:53807-409-04 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/16/1999 | |
| **2** | NDC:53807-409-08 | 236 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/16/1999 | |
| **3** | NDC:53807-409-16 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/16/1999 | |
| **4** | NDC:53807-409-28 | 3785 mL in 1 BOTTLE; Type 0: Not a Combination Product | 03/16/1999 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part341 | 03/16/1999 | |

## Labeler - Rij Pharmaceutical Corporation (144679156)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Rij Pharmaceutical Corporation | | 144679156 | manufacture(53807-409) |

Revised: 4/2018 Rij Pharmaceutical Corporation