**ORGAN-I NR- guaifenesin tablet**
**Carilion Materials Management**

*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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**ORGAN-I NR**

***Active ingredient***

Guaifenesin, USP 200 mg

***Purpose***

Expectorant

***Use***

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

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. **Stop use and ask a doctor if**

ask a health professional before use. **If pregnant or breast-feeding,**

**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
- this adult product is not intended for use in children under 12 years of age

| | |
|---|---|
| adults and children 12 years and over | 1 - 2 tablets every 4 hours |
| children under 12 years | do not use |

***Other information***

- store at 15° to 30°C (59° to 86°F)

You may report serious side effects to: . *130 Vintage Drive, Huntsville, AL 35811*

***Inactive ingredients***

D&C red #30 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyvinylpyrrolidine, pregelatinized starch, silicon dioxide, stearic acid

Made in the for Qualitest Pharmaceuticals Huntsville, AL 35811 **USA**

Rev. 3/11 R5 8080143 4740

**HOW SUPPLIED**

Product: 68151-1929

NDC: 68151-1929-2 1 TABLET in a PACKAGE

**Guaifenesin 200 MG TAB**


## ORGAN-I NR

guaifenesin tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:68151-1929(NDC:0603-4886) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **D&C RED NO. 30** (UNII: 2S42T2808B) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |

| | |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | RED (rose colored) | **Score** | 2 pieces |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | 4740;V |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:68151-1929-2 | 1 in 1 PACKAGE; Type 0: Not a Combination Product | 07/01/2002 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part341 | 07/01/2002 | |

## Labeler - Carilion Materials Management (079239644)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Carilion Materials Management | | 079239644 | REPACK(68151-1929) |

Revised: 12/2017 Carilion Materials Management