**MUCUS RELIEF CHEST CONGESTION- guaifenesin tablet, film coated**
**Major Pharmaceuticals**

*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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**Major 44-532**

***Active ingredient (in each immediate-release tablet)***

Guaifenesin 400 mg

***Purpose***

Expectorant

***Uses***

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

***Warnings***

**Ask a doctor before use if you have**

- cough accompanied by too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Stop use and ask a doctor if**

cough persists more than 7 days, tends to recur, or is accompanied by a 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 (1-800-222-1222) right away.

***Directions***

- take with a full glass of water
- adults and children 12 years and over: 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- children under 12 years: do not use

***Other information***

- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- use by expiration date on package

***Inactive ingredients***

FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

***Questions or comments?***
**(800) 616-2471**

**Principal Display Panel**

**Major®**

**NDC 0904-6815-46**

**Mucus Relief**
Chest Congestion

Guaifenesin 400 mg

Expectorant

*Actual Size*

•*Relieves Chest Congestion*
•*Thins and Loosens Mucus*

*Immediate Release*

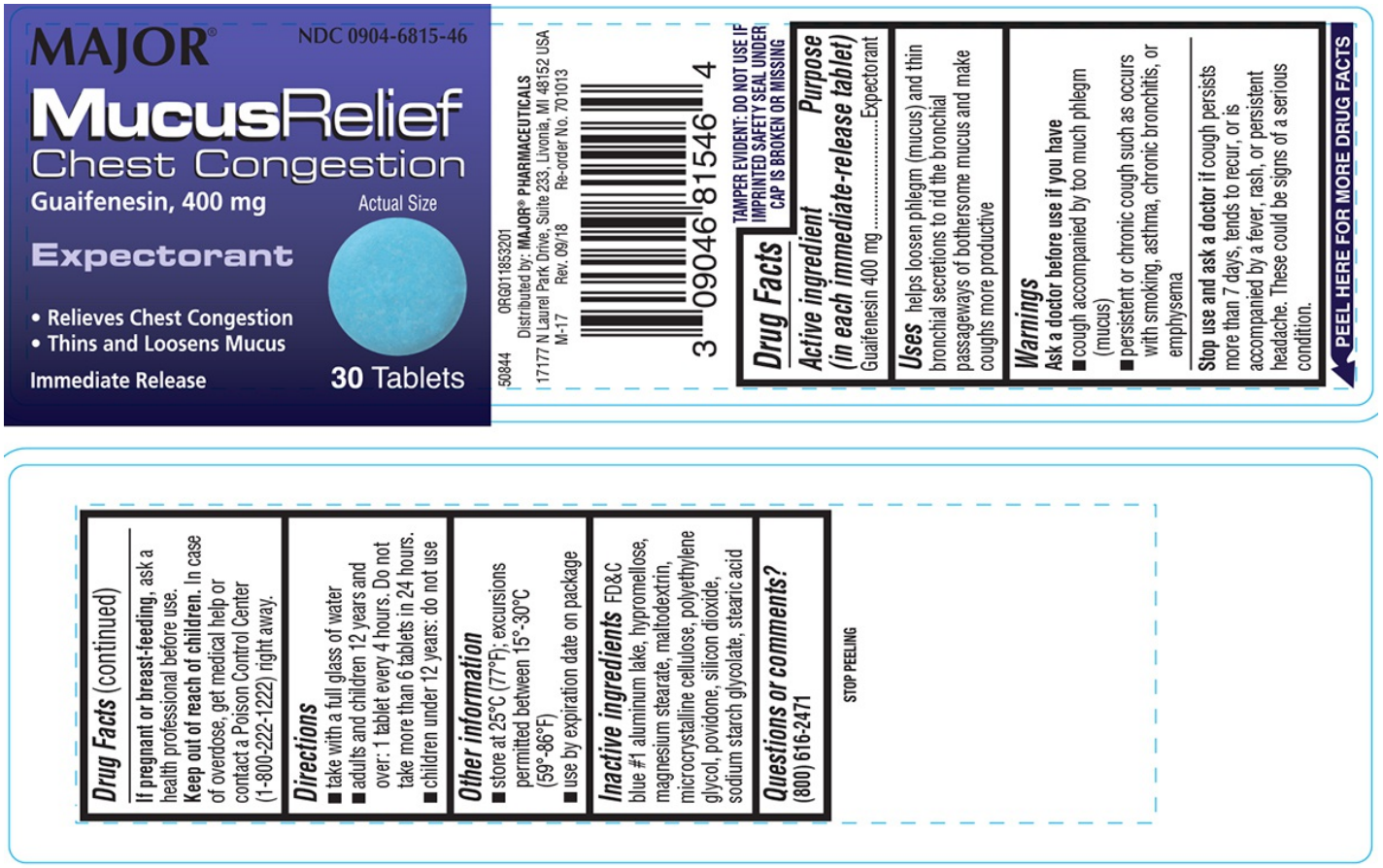
***30** Tablets*

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

50844 ORG011853201

Distributed by: **MAJOR® PHARMACEUTICALS**
17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152 USA

M-17 Rev. 09/18 Re-order No. 701013




**Major 44-532**

# MUCUS RELIEF CHEST CONGESTION

guaifenesin tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:0904-6815 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 400 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |

| | |
|---|---|
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | BLUE | **Score** | 2 pieces |
| **Shape** | ROUND | **Size** | 13mm |
| **Flavor** | | **Imprint Code** | 44;532 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0904-6815-46 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 10/31/2018 | |
| **2** | NDC:0904-6815-52 | 60 in 1 BOTTLE; Type 0: Not a Combination Product | 10/31/2018 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part341 | 10/31/2018 | |

## Labeler - Major Pharmaceuticals (191427277)

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | MANUFACTURE(0904-6815) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 967626305 | PACK(0904-6815) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | PACK(0904-6815) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 038154464 | PACK(0904-6815) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 868734088 | PACK(0904-6815) |