**GUAIFENESIN AND DEXTROMETHORPHAN HBR- guaifenesin and dextromethorphan hbr tablet, extended release**
**Kroger Company**

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**Guaifenesin and Dextromethorphan HBr**

***Drug Facts***

| ***Active ingredients (in each extended-release tablet)*** | ***Purposes*** |
|---|---|
| Dextromethorphan HBr 60 mg | Cough suppressant |
| Guaifenesin 1,200 mg | Expectorant |

**Uses**

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help you get to sleep

**Warnings**

**Do not use**

- for children under 12 years of age
- 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**

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

**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 occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

**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 (1-

800-222-1222).

**Directions**

- do not crush, chew, or break extended-release tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 1 extended-release tablet every 12 hours; not more than 2 extended-release tablets in 24 hours
- children under 12 years of age: do not use

**Other information**

- Store between 20-25°C (68-77°F)

**Inactive ingredients**

carbomer homopolymer, colloidal silicon dioxide, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone (K-30), stearic acid

**Questions?**

***1-800-632-6900***

You may also report side effects to this phone number.

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202

**PRINCIPAL DISPLAY PANEL - 14 Extended-Release Tablet Blister Pack Carton**

COMPARE TO the active ingredients of
MAXIMUM STRENGTH Mucinex® DM

NDC 30142-963-14

Kroger®

OUR PHARMACIST RECOMMENDED

Maximum Strength

Mucus Relief
ER DM - Max
Guaifenesin 1200 mg &
Dextromethorphan HBr 60 mg
Extended-Release
Tablets

EXPECTORANT &
COUGH SUPPRESSANT

12

Hour

- Controls Cough
- Thins & Loosens Mucus
- Immediate & Extended Release

14 EXTENDED-RELEASE
TABLETS

Maximum Strength

# Mucus Relief ER DM-Max

Guaifenesin 1200 mg & Dextromethorphan HBr 60 mg
Extended-Release Tablets
EXPECTORANT & COUGH SUPPRESSANT

COMPARE TO the active ingredients of
MAXIMUM STRENGTH Mucinex® DM *See back panel

NDC 30142-963-14

OUR PHARMACIST RECOMMENDED

Maximum Strength

# Mucus Relief ER DM-Max

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Dextromethorphan HBr 60 mg
Extended-Release
Tablets

EXPECTORANT &
COUGH SUPPRESSANT

- Controls Cough
- Thins & Loosens Mucus
- Immediate & Extended Release

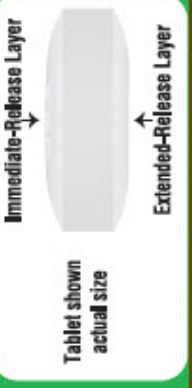
actual size


12 HOUR

14 EXTENDED-RELEASE TABLETS

Lot No.

Expiration Date:


PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

NON VARNISH

5230548

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# Drug Facts (continued)

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## Questions or comments?

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**DISTRIBUTED BY THE KROGER CO.**
**CINCINNATI, OHIO 45202**

**PRODUCT OF INDIA**

**QUALITY GUARANTEE**
**800-632-6900 | www.kroger.com**

*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Mucinex® DM.

**KEEP THE CARTON. IT CONTAINS IMPORTANT INFORMATION. SEE END PANEL FOR EXPIRATION DATE.**

0322

PLEASE RECYCLE

GLUE - NO COATING

5230548

# GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:30142-963 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 1200 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 60 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)** (UNII: HHT01ZNK31) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **POVIDONE K30** (UNII: U725QWY32X) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE (off-white) | **Score** | no score |
| **Shape** | OVAL | **Size** | 16mm |
| **Flavor** | | **Imprint Code** | 053 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:30142-963-14 | 1 in 1 CARTON | 05/23/2022 | |
| **1** | | 14 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:30142-963-28 | 2 in 1 CARTON | 05/23/2022 | |
| **2** | | 14 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA214781 | 05/23/2022 | |

## Labeler - Kroger Company (006999528)

## Registrant - SUN PHARMACEUTICAL INDUSTRIES, INC. (146974886)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Sun Pharmaceutical Industries Limited | | 650456002 | MANUFACTURE(30142-963) |

Revised: 5/2022 Kroger Company