

GUAIFENESIN AND DEXTROMETHORPHAN HBR - guaifenesin and dextromethorphan hbr tablet, extended release
TOPCO ASSOCIATES LLC

Drug Facts

Active ingredients

(in each extended-release tablet)

Dextromethorphan Hydrobromide USP 60 mg
Guaifenesin USP 1200 mg

Purposes

Cough suppressant
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 (1-800-222-1222) right away.

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 at 20° to 25°C (68° to 77°F)

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch (maize)

Questions?

call **1-855-274-4122**

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ITASCA, IL 60143 ©TOPCO ARHA0825

QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com

MADE IN INDIA

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 60 mg/1200 mg Blister Carton
56 (8 x 7) Unit-Dose Tablets**

**TopCare®
health**

NDC 76162-032-56

**COMPARE TO THE ACTIVE
INGREDIENTS OF MAXIMUM
STRENGTH MUCINEX® DM***

**MAXIMUM STRENGTH
Mucus DM**

DEXTROMETHORPHAN HBr and GUAIFENESIN
EXTENDED-RELEASE TABLETS
60 mg/1200 mg

DEXTROMRTHORPHAN HBr 60 mg - COUGH SUPPRESSANT
GUAIFENESIN 1200 mg - EXPECTORANT

RELIEVES COUGH & CHEST CONGESTION

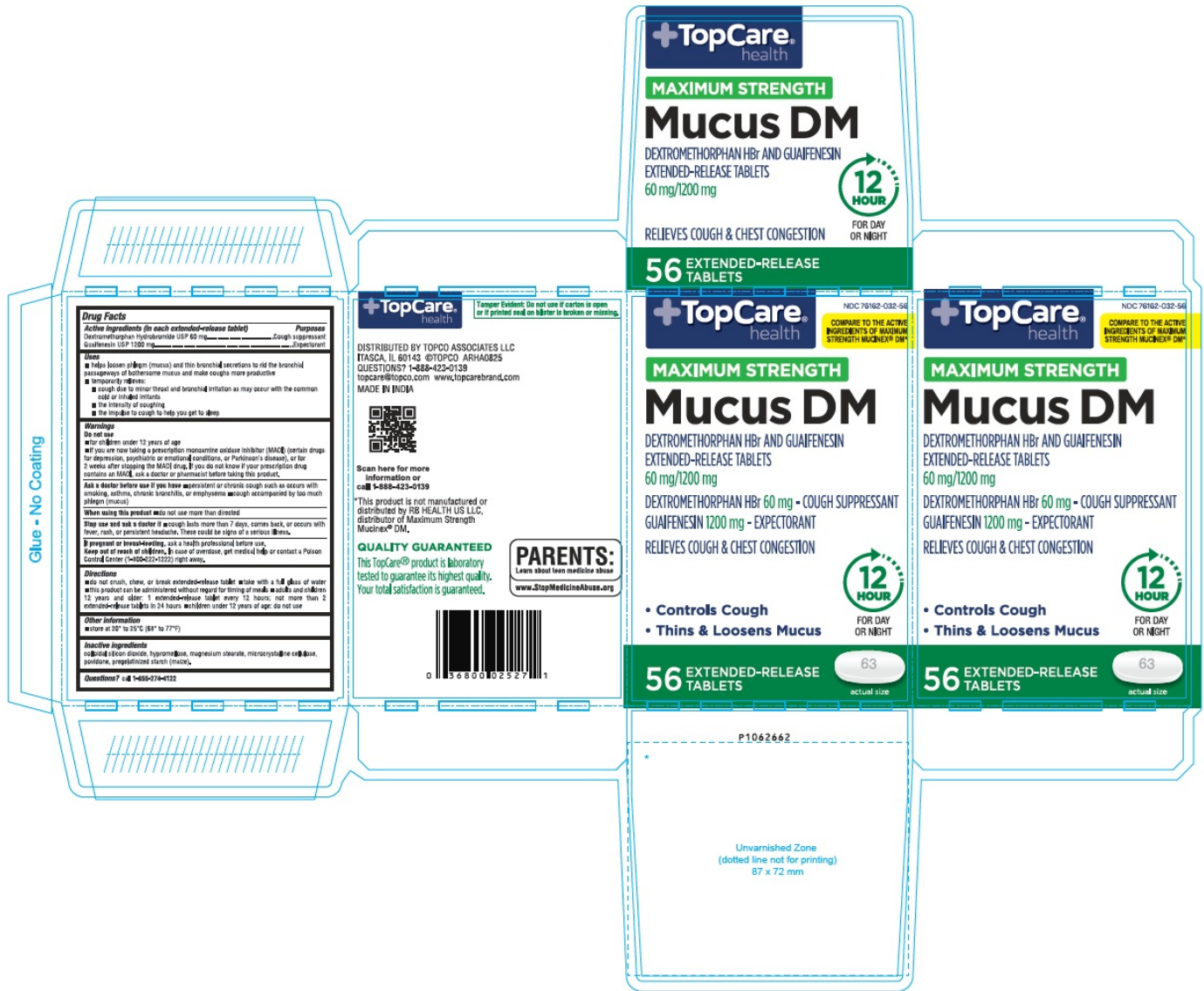
**12
HOUR**

- **Controls Cough**
- **Thins & Loosens Mucus**

FOR DAY
OR NIGHT

**56 EXTENDED-RELEASE
TABLETS**

actual size



GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76162-032 |
| 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 |
|-----------------|----------|
|-----------------|----------|

| | |
|--|--|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I3O) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POVIDONE K90 (UNII: RDH86HJV5Z) | |
| POVIDONE K25 (UNII: K0KQV10C35) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |

Product Characteristics

| | | | |
|-----------------|----------------------------|---------------------|----------|
| Color | WHITE (white to off-white) | Score | no score |
| Shape | OVAL | Size | 22mm |
| Flavor | | Imprint Code | X;63 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:76162-032-56 | 8 in 1 CARTON | 04/23/2026 | |
| 1 | | 7 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 | ANDA206941 | 04/23/2026 | |

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - Aurohealth LLC (078728447)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|--|
| Aurobindo Pharma Limited | | 650381903 | ANALYSIS(76162-032) , MANUFACTURE(76162-032) |

Revised: 4/2026

TOPCO ASSOCIATES LLC