

**GUAIFENESIN AND DEXTROMETHORPHAN HBR - guaifenesin and dextromethorphan
hbr tablet, extended release
Aurohealth LLC**

Drug Facts

Active ingredients

(in each extended-release tablet)

Dextromethorphan Hydrobromide USP 60 mg

Guaifenesin USP 1200 mg

Purpose

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 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 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- tamper evident: do not use if carton is open or if printed seal on blister is broken or missing
- 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 You may also report side effects to this phone number.

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 1200 mg/60 mg 14 (2 x 7) Tablets Carton Label

HealthyLiving

NDC 58602-849-65

Compare to the active ingredients of
Maximum Strength Mucinex® DM*

MAXIMUM STRENGTH

Mucus Relief DM

Guaifenesin and Dextromethorphan HBr

Extended-release Tablets 1200 mg/60 mg

EXPECTORANT AND COUGH SUPPRESSANT

Controls Cough
Thins and Loosens Mucus

12
HOUR

63
14 (2 x 7) Extended-release Tablets



GUAIFENESIN AND DEXTROMETHORPHAN HBR

guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58602-849 |
| 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: 70097M6I30) | | | | |
| 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:58602-849-65 | 2 in 1 CARTON | 05/16/2020 | |
| 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 | | 05/16/2020 | |

Labeler - Aurohealth LLC (078728447)

| Establishment | | | |
|--------------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Aurobindo Pharma Limited | | 650381903 | ANALYSIS(58602-849) , MANUFACTURE(58602-849) |