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

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Drug Facts

Active Ingredients

(in each extended-release tablet)

Dextromethorphan Hydrobromide USP 30 mg
Guaifenesin USP 600 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 or 2 tablets every 12 hours; not more than 4 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.
**Drug Facts**

**Active ingredients (in each extended-release tablet)**
- Dextromethorphan Hydrobromide USP 30 mg: Cough suppressant
- Guaifenesin USP 600 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.
- 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 or 2 tablets every 12 hours; not more than 4 tablets in 24 hours.
- Children under 12 years of age: do not use.

**Other Information**
- Tamper evident: do not use if seal over bottle opening is broken or missing.
- Store at 20° to 25°C (68° to 77°F).

**Inactive ingredients**
- Colloidal silicon dioxide, hyromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch (maltz)

**Questions?** Call 1-855-274-4122. You may also report side effects to this phone number.
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/30 mg (14 Tablet Carton Label)

Compare to the active ingredients of Mucinex® DM*
NDC 58602-714-05
Mucus Relief DM
Guaifenesin and Dextromethorphan HBr
Extended-release Tablets
600 mg/30 mg
EXPECTORANT AND COUGH SUPPRESSANT
12 HOUR
Controls Cough
Thins and Loosens Mucus
14 Extended-release Tablets
AUROHEALTH
PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 600 mg/30 mg Blister Carton 20 (2 x 10) Unit-dose Tablets

Compare to the active ingredients of Mucinex® DM*

NDC 58602-714-67
Mucus Relief DM
Guaifenesin and Dextromethorphan HBr
Extended-release Tablets
600 mg/30 mg
EXPECTORANT AND COUGH SUPPRESSANT
12 HOUR
Controls Cough
Thins and Loosens Mucus
20 (2 x 10) Extended-release Tablets
AUROHEALTH
GUAIFENESIN AND DEXTROMETHORPHAN HBR
guaifenesin and dextromethorphan hbr tablet, extended release

**Product Information**

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<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
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<td>Route of Administration</td>
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**Active Ingredient/Active Moeity**

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)</td>
<td>GUAIFENESIN</td>
<td>600 mg</td>
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<td>DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KYH)</td>
<td>DEXTROMETHORPHAN</td>
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<td>(DEXTROMETHORPHAN - UNII:7355X3ROTS)</td>
<td>HYDROBROMIDE</td>
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**Inactive Ingredients**

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<tr>
<td>SILICON DIOXIDE (UNII: ETJ7Z6XBU4)</td>
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<td>HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)</td>
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<td>MAGNESIUM STEARATE (UNII: 700976BD30)</td>
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<td>MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)</td>
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<td>Product Characteristics</td>
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<td><strong>Color</strong></td>
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<tr>
<td><strong>Shape</strong></td>
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<td><strong>Size</strong></td>
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| Imprint Code | X;62 |

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**Labeler** - Aurohealth LLC (078728447)

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Revised: 10/2019