Drug Facts

Active ingredients (in each extended-release tablet)
Dextromethorphan HBr 60 mg
Guaifenesin 1200 mg

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.

**Pregnancy or Breast Feeding**

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

**Package/Label Principal Display Panel**

NDC 63304-110-14

**Maximum Strength**

Guaifenesin & Dextromethorphan HBr Extended-Release Tablets

1200 mg/60 mg

**Expectorant & Cough Suppressant**

12 Hour

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

**14 Extended-Release Tablets**
Package/Label Principal Display Panel

NDC 63304-106-21

Guaifenesin & Dextromethorphan HBr Extended-Release Tablets
600 mg/30 mg

Expectorant & Cough Suppressant

12 Hour

• Controls Cough
• Thins and Loosens Mucus
• Immediate and Extended Release

20 Extended-Release Tablets

SUN PHARMA
GUAIFENESIN AND DEXTROMETHORPHAN HBr
guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

Product Type: HUMAN OTC DRUG
Route of Administration: ORAL

Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)</td>
<td>GUAIFENESIN</td>
<td>600 mg</td>
</tr>
<tr>
<td>DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)</td>
<td>DEXTROMETHORPHAN HYDROBROMIDE</td>
<td>30 mg</td>
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</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
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</tr>
</thead>
<tbody>
<tr>
<td>HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6I30)</td>
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</tr>
</tbody>
</table>
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
MALTODEXTRIN (UNII: 7CVR7L42A2D)
POVIDONE K30 (UNII: U725QWY32X)
STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>Color</td>
<td>WHITE (off-white)</td>
</tr>
<tr>
<td>Score</td>
<td>no score</td>
</tr>
<tr>
<td>Shape</td>
<td>OVAL</td>
</tr>
<tr>
<td>Size</td>
<td>16mm</td>
</tr>
<tr>
<td>Flavor</td>
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</tr>
<tr>
<td>Imprint Code</td>
<td>054</td>
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</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:63304-106-21</td>
<td>1 in 1 CARTON</td>
<td>07/01/2021</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>20 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
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Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
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<th>Marketing End Date</th>
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<tbody>
<tr>
<td>ANDA</td>
<td>ANDA214781</td>
<td>07/01/2021</td>
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GUAIFENESIN AND DEXTROMETHORPHAN HBR
guaifenesin and dextromethorphan hbr tablet, extended release

Product Information

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<thead>
<tr>
<th>Product Type</th>
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### Labeler
- SUN PHARMACEUTICAL INDUSTRIES, INC. (146974886)

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

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Sun Pharmaceutical Industries Limited</td>
<td></td>
<td>650456002</td>
<td>MANUFACTURE(63304-110, 63304-106)</td>
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</tbody>
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Revised: 12/2022