PRIMATENE- ephedrine hcl, guaifenesin tablet
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

----------

Drug Facts

ACTIVE INGREDIENTS (IN EACH TABLET)
Ephedrine HCl, USP 12.5 mg
Guaifenesin, USP 200 mg

PURPOSES
Bronchodilator
Expectorant

USES
• for temporary relief of mild symptoms of intermittent asthma:
  • wheezing
  • tightness of chest
  • shortness of breath
• helps loosen phlegm (mucus) and thin bronchial secretions to rid bronchial passageways of bothersome mucus, and to make coughs more productive

WARNINGS

Asthma alert
Because asthma may be life threatening, see a doctor if you
• are not better in 60 minutes
• get worse
• need more than 12 tablets in 24 hours
• use more than 8 tablets in 24 hours for 3 or more days a week
• have more than 2 asthma attacks in a week

These may be signs that your asthma is getting worse
• This product will not give you asthma relief as quickly as an inhaled bronchodilator

Do not use
• unless a doctor said you have asthma
• if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs taken 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**

• ever been hospitalized for asthma
• heart disease
• high blood pressure
• diabetes
• thyroid disease
• seizures
• narrow angle glaucoma
• a psychiatric or emotional condition
• trouble urinating due to an enlarged prostate gland
• cough that occurs with too much phlegm (mucus)
• cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Ask a doctor or pharmacist before use if you are**

• taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions
• taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain)

**Stop use and ask a doctor if**

• your asthma is getting worse (see Asthma alert)
• you have difficulty sleeping
• you have a rapid heart beat
• you have tremors, nervousness, or seizure
• cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**When using this product**

• **your blood pressure or heart rate may go up. This could increase your risk of heart attack or stroke, which may cause death.**
• **your risk of heart attack or stroke increases if you:**
  • have a history of high blood pressure or heart disease
  • take this product more frequently or take more than the recommended dose

• avoid foods or beverages that contain caffeine
• avoid dietary supplements containing ingredients reported or claimed to have a
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.

DIRECTIONS

• do not take more than directed

<table>
<thead>
<tr>
<th>age</th>
<th>dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>adults and children 12 years of age and over</td>
<td>oral dose is 1-2 tablets (12.5 to 25 mg) every 4 hours as needed. Do not take more than 12 tablets (150 mg) in 24 hours</td>
</tr>
<tr>
<td>children under 12 years of age</td>
<td>ask a doctor</td>
</tr>
</tbody>
</table>

OTHER INFORMATION

• store at 20-25°C (68-77°F)

INACTIVE INGREDIENTS

colloidal silicon dioxide, crospovidone, D&C yellow no. 10 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, povidone

QUESTIONS OR COMMENTS?

Call weekdays from 9 AM to 5 PM EST at 1-800-535-0026

For most recent product information, visit www.PrimateneTablets.com

PRINCIPAL DISPLAY PANEL

NDC 0573-2952-20

Primatene®
TABLETS

Ephedrine HCl, Bronchodilator/Guaifenesin, Expectorant
Helps Loosen Phlegm (Mucus)

For the Temporary Relief of Mild Symptoms of
INTERMITTENT ASTHMA

60 TABLETS
PRIMATENE
ephedrine hcl, guaifenesin tablet

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>EPHEDRINE HYDROCHLORIDE (UNII: NLJ6390P1Z) (EPHEDRINE - UNII:GN83C131XS)</td>
<td>EPHEDRINE HYDROCHLORIDE</td>
<td>12.5 mg</td>
</tr>
<tr>
<td>GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)</td>
<td>GUAIFENESIN</td>
<td>200 mg</td>
</tr>
</tbody>
</table>

Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>SILICON DIOXIDE (UNII: ETJ7Z6XBU4)</td>
<td></td>
</tr>
<tr>
<td>CROSPVIDONE (UNII: 2S7830E561)</td>
<td></td>
</tr>
<tr>
<td>D&amp;C YELLOW NO. 10 (UNII: 355W5USQ3G)</td>
<td></td>
</tr>
<tr>
<td>FD&amp;C YELLOW NO. 6 (UNII: H77VEI93A8)</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6I30)</td>
<td></td>
</tr>
<tr>
<td>MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)</td>
<td></td>
</tr>
<tr>
<td>Povidone, unspecified (UNII: FZ989GH94E)</td>
<td></td>
</tr>
</tbody>
</table>

Product Characteristics

Color: YELLOW (Light yellow color)
Score: no score
Shape: ROUND
Size: 8mm
Flavor:  
Imprint Code: P;in;circle;engraved;bisect

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:0573-2952-10</td>
<td>2 in 1 CARTON</td>
<td>01/06/2004</td>
<td>06/30/2023</td>
</tr>
<tr>
<td>1</td>
<td>NDC:0573-2952-20</td>
<td>12 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td>01/06/2004</td>
<td>06/30/2023</td>
</tr>
<tr>
<td>2</td>
<td>NDC:0573-2952-10</td>
<td>5 in 1 CARTON</td>
<td>01/06/2004</td>
<td>06/30/2023</td>
</tr>
<tr>
<td>2</td>
<td>NDC:0573-2952-20</td>
<td>12 in 1 BLISTER PACK; Type 0: Not a Combination Product</td>
<td>01/06/2004</td>
<td>06/30/2023</td>
</tr>
</tbody>
</table>
### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>OTC monograph final</td>
<td>part341</td>
<td>01/06/2004</td>
<td>06/30/2023</td>
</tr>
</tbody>
</table>

**Labeler** - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wyeth Pharmaceuticals Company</td>
<td></td>
<td>829390975</td>
<td>ANALYSIS(0573-2952), LABEL(0573-2952), MANUFACTURE(0573-2952), PACK(0573-2952)</td>
</tr>
</tbody>
</table>

Revised: 6/2021