DESGEN PEDIATRIC- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops
Kramer Novis

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 1 mL)  Purpose
Dextromethorphan HBr, 5 mg...............Antitussive
Guaifenesin, 50 mg.........................Expectorant
Phenylephrine HCl, 2.5 mg...............Nasal decongestant

Uses

• helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive

• temporarily relieves:
  • nasal congestion due to the common cold
  • cough due to minor throat and bronchial irritation as may occur with the common cold

Warnings

Do not use
in child who is 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 child's prescription drug contains a MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if your child has
• heart disease
• thyroid disease
• high blood pressure
• diabetes
• a cough that occurs with too much phlegm (mucus)
• cough that lasts or is chronic such as occurs with asthma

When using this product do not exceed recommended dosage

Stop use and ask a doctor if
• new symptoms occur
• your child gets nervous, dizzy or sleepless
• symptoms do not get better within 7 days or are accompanied by fever
• cough last more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be a signs of a serious condition.
If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

**Directions**
do not use more than 6 doses in any 24-hour period

**Children 2 to under 5 years of age**
- 1 mL every 4 hours, do not exceed 6 doses, or as directed by a doctor.

**Children under 2, consult a doctor.**
- measure with the dosage device provided. Do not use any other device.

**Other information**
Tamper Evident Feature: Do not use if cap seal is torn, broken or missing.
Store at controlled room temperature 15-30°C (59-86°F).
Avoid excessive heat and humidity.

**Inactive ingredients** Citric acid, flavors, glycerin, methyl paraben, polyethylene glycol, propylene glycol, propyl paraben, purified water, sodium citrate, sorbitol and sucralose.
Manufactured in the USA for Kramer-Novis, San Juan, PR 00917. Tel: (787) 767-2072

**Principal Display Panel**
DESGEN
PEDIATRIC DROPS
Contains the same active ingredients as Despec® EDA drops
Antitussive
Expectorant
Nasal Decongestant
Sugar, Alcohol & Dye Free
NET CONTENT: 30 mL (1 Fl. Oz.)
KRAMER-NOVIS
DESGEN PEDIATRIC

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN OTC DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:52083-641</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT9KY9) (DEXTROMETHORPHAN - UNII:7355X3ROTS)</td>
<td>DEXTROMETHORPHAN HYDROBROMIDE</td>
<td>5 mg in 1 mL</td>
</tr>
<tr>
<td>GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)</td>
<td>GUAIFENESIN</td>
<td>50 mg in 1 mL</td>
</tr>
<tr>
<td>PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)</td>
<td>PHENYLEPHRINE HYDROCHLORIDE</td>
<td>2.5 mg in 1 mL</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)</td>
<td></td>
</tr>
<tr>
<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
<td></td>
</tr>
<tr>
<td>METHYLPARABEN (UNII: A2Bc7H9T)</td>
<td></td>
</tr>
<tr>
<td>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)</td>
<td></td>
</tr>
<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
<td></td>
</tr>
<tr>
<td>PROPYLPARABEN (UNII: Z8IX2SC1OH)</td>
<td></td>
</tr>
<tr>
<td>WATER (UNII: 059QF0KO0R)</td>
<td></td>
</tr>
<tr>
<td>SODIUM CITRATE, UNSPECIFIED FORM (UNII: IQ7Q2JULR)</td>
<td></td>
</tr>
<tr>
<td>SORBITOL (UNII: 506T60A25R)</td>
<td></td>
</tr>
<tr>
<td>SUCRALOSE (UNII: 96K6UQ3ZD4)</td>
<td></td>
</tr>
</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:52083-641-01</td>
<td>30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product</td>
<td>01/27/2014</td>
<td></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>01/27/2014</td>
<td></td>
</tr>
</tbody>
</table>

---

**Labeler** - Kramer Novis (090158395)

Revised: 9/2019