**SUPRESS-PE PEDIATRIC- guiafenesin, 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.*

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**SUPRESS-PE Pediatric**

***Drug Facts***

***Active Ingredients (in each 1 mL)***

Guaifenesin, 50 mg

Phenylephrine HCl, 2.5 mg

***Purpose***

Expectorant

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

***Warnings***

***Do not use*** in a 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 the child has***

• heart disease • thyroid disease • high blood pressure • diabetes
• 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**

• 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.

**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

• repeat every 4 hours
• measure with the dosage device provided. Do not use with any other device

| age | dose |
|---|---|
| children 2 years to under 6 years of age | 1 mL |
| children under 2 years of age | Consult a doctor |

***Other information***

• Tamper Evident Feature: Do not use if cap seal is torn, broken or missing. For your protection, this bottle has an imprinted seal around the neck.
• Store at controlled room temperature 15-30°C (59-86°F).
• Avoid excessive heat and humidity.

***Inactive ingredients***

Citric acid, glycerin, grape flavor, methylparaben, polyethylene glycol, purified water, propylene glycol, propylparaben, sodium citrate, sucralose and sucrose.

**SUPRESS-PE**

**PEDIATRIC DROPS**

**EXPECTORANT**

**NASAL-DECONGESTANT**

**Great Grape Flavor**

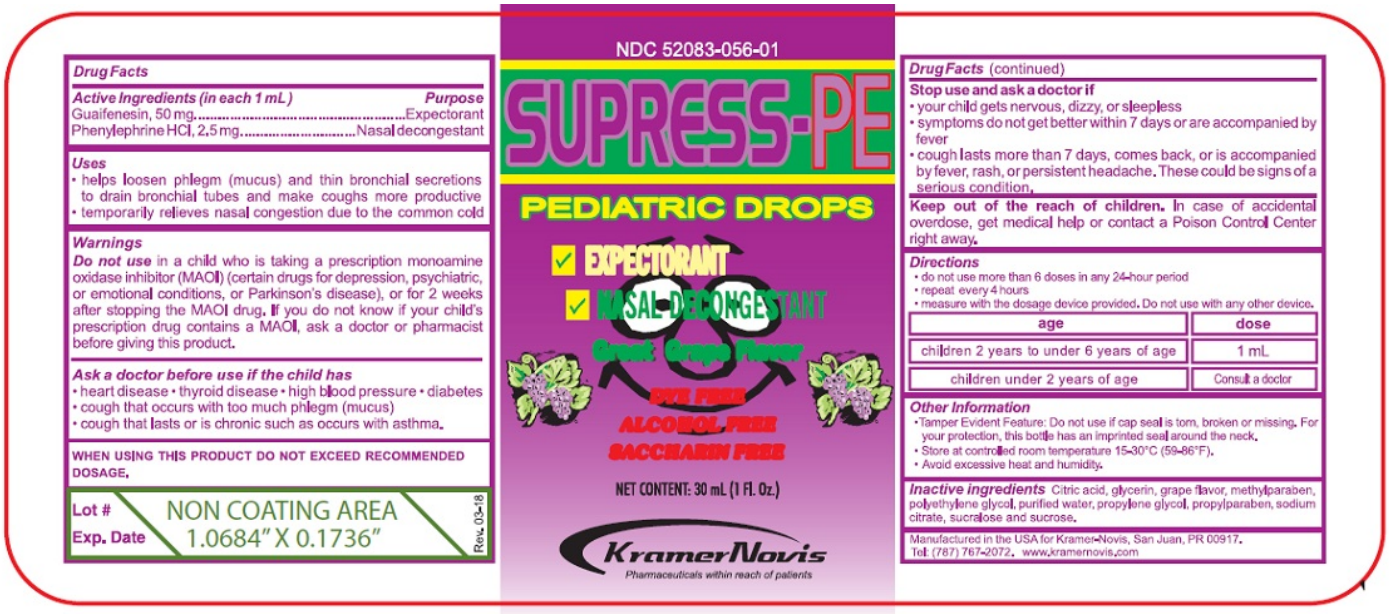
**DYE FREE**

**ALCOHOL FREE**

**SACCHARINE FREE**

Manufactured in the USA for Kramer-Novis, San Juan, PR 00917. Tel: (787) 767-2072
www.kramernovis.com

**Packaging**



# SUPRESS-PE PEDIATRIC

guiafenesin, phenylephrine hcl solution/ drops

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:52083-056 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 50 mg in 1 mL |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 2.5 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **SODIUM CITRATE, UNSPECIFIED FORM** (UNII: 1Q73Q2JULR) | |
| **SUCRALOSE** (UNII: 96K6UQ3ZD4) | |
| **SUCROSE** (UNII: C151H8M554) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:52083-056-01 | 30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 01/14/2014 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 01/14/2014 | |

## Labeler - Kramer Novis (090158395)

Revised: 11/2018 Kramer Novis