

**SUPRESS DX PEDIATRIC DROPS- dextromethorphan hydrobromide,
guaifenesin, phenylephrine hydrochloride syrup
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.

SUPRESS-DX PEDIATRIC DROPS

Drug Facts

Active Ingredients (in each 1 mL)

Dextromethorphan HBr, 5mg

Guaifenesin, 50mg

Phenylephrine HCl, 2.5mg

Purposes

Cough Suppressant

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 hay fever or other upper respiratory allergies (allergic rhinitis)
 - cough due to minor throat and bronchial irritation as may occur with the common cold

Warnings

- **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
- children 2 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.
- Store at controlled room temperature 15-30°C (59-86°F)

Inactive Ingredients

- Citric acid, FD&C Red 40, Flavor, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water and Sucralose.

Questions or comments?

call weekdays from 8 am to 4 pm AST at **1.787.767.2072**


Sugar & Alcohol Free

Kramer Novis Pharmaceuticals within reach of patients

Manufactured in the USA for Kramer Novis, San Juan, PR 00917.
www.kramernovis.com

RETAIN CARTON FOR FULL PRESCRIBING INFORMATION

Packaging



<p>Drug Facts</p> <p>Active Ingredients (in each 1 mL) Purposes Dextromethorphan HBr, 5 mg. Cough Suppressant Guaifenesin, 50 mg..... Expectorant Phenylephrine HCl, 2.5 mg.... Nasal Decongestant</p>	<p>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 ■ children 2 to under 6 years of age: 1 mL ■ children under 2 years of age: Consult a doctor.</p>
<p>Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive ■ temporarily relieves: ■ nasal congestion due to hay fever or other upper respiratory allergies (allergic rhinitis) ■ cough due to minor throat and bronchial irritation as may occur with the common cold</p>	<p>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)</p>
<p>Warnings ■ Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away,</p>	<p>Inactive ingredients ■ Citric acid, FD&C Red 40, Flavor, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, and Sucralose.</p> <p>Questions or comments? call weekdays from 8 am to 4 pm AST at 1.787.767.2072</p>

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SUPRESS DX PEDIATRIC DROPS			
dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride syrup			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-055
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	red (CHERRY RED)	Score	
Shape		Size	
Flavor	CHERRY (SOUR CHERRY)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-055-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/29/2011	

Labeler - KRAMER NOVIS (090158395)

Registrant - KRAMER NOVIS (090158395)