

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 1mL)

Dextromethorphan HBr, 5mg

Guaifenesin, 50mg

Phenylephrine HCl, 2.5mg

Purpose

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

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 an 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 lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache.
- These could be 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.
- **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. 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, FD&C red 40, flavor, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate and sodium saccharin.

COUGH SUPPRESSANT

EXPECTORANT

NASAL DECONGESTANT

NO SUGAR ALCOHOL

Manufactured in the USA for Kramer-Novis

San Juan, PR 00917 • Tel: (787) 767-2072

Packaging

Lot No.	Drug Facts	NDC 52083-055-01 SUPPRESS-DX PEDIATRIC DROPS ✓ COUGH SUPPRESSANT ✓ EXPECTORANT ✓ NASAL DECONGESTANT Great Cherry Flavor NO SUGAR ALCOHOL NET CONTENT: 30 ML (1 Fl. Oz.) SEE CARTON FOR FULL PRESCRIBING INFORMATION KramerNovis Pharmaceuticals with reach of patients	Drug Facts continued
	Active Ingredients (in each 1mL) Purpose Dextromethorphan HBr, 5mg Cough Suppressant Guaifenesin, 50mg Expectorant Phenylephrine HCl, 2.5mg 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 the 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.		
Exp. Date			07/2018

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: 9D2RTI9KYH) (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: 059QF0K00R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

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 NO VIS (090158395)

Registrant - KRAMER NO VIS (090158395)

Revised: 12/2018

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