SUPRESS A- dexbromopheniramine maleate, dextromethorphan hbr, phenylephrine hcl 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 A

Active ingredients (in each 1 mL)

Dexbrompheniramine Maleate, 1 mg

Dextromethorphan HBr, 10 mg

Phenylephiren HCl, 5 mg

Purpose

Antihistamine

Cough suppressant

Expectorant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- sneezing
- itchy nose or throat
- runny nose
- itchy, watery eyes
- nasal congestion
- temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants
- temporarily restores freer breathing through nose

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 taking this product.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or occurs with smoking, asthma, chronic bronchitis, or emphysema
- **Ask a doctor or pharmacist before use if the child** is taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- may cause marked drowsiness
- sedative and tranquilizers may increase drowsiness effect

Stop use and ask a doctor if

- nervousness dizziness, or sleeplessness occur
- new symptoms occur
- symptoms do not improve 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.

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

Children 6 to under 12 years of age

- 1 mL every 4 hours as needed, do not exceed 6 doses in any 24-hour, or as directed by a doctor
- Children under 6, consult a doctor.
- measure with the dosage device provided. Do not use any other device

Other information

- Tamper evident feature: Do not use if inner seal is torn, broken or missing.
- Store at controlled room temperature 15°-30°C (59° to 86°F).
- Avoid excessive heat and humidity.

Inactive ingredients

Citric acid, flavor, glycerin, methylparaben, polysorbate, propylene glycol, propyl paraben, purified water, sodium citrate and sucralose.

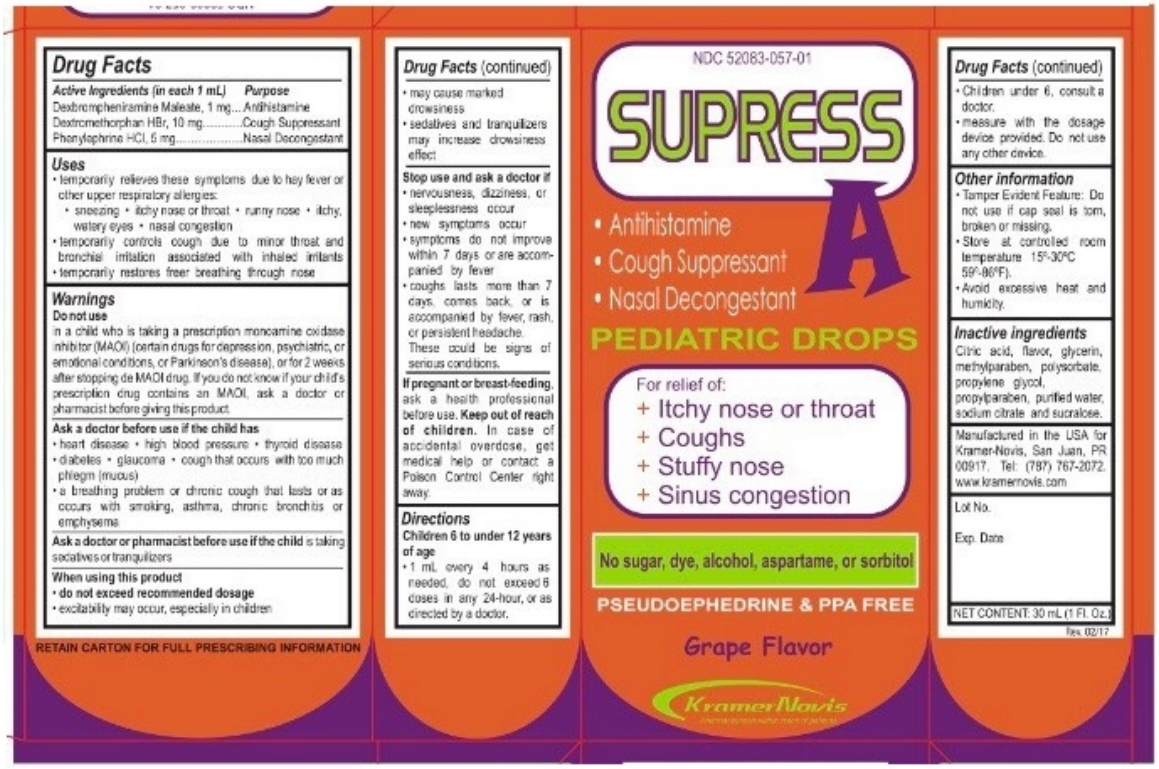
Made in the USA for Kramer Novis.

San Juan, PR 00917

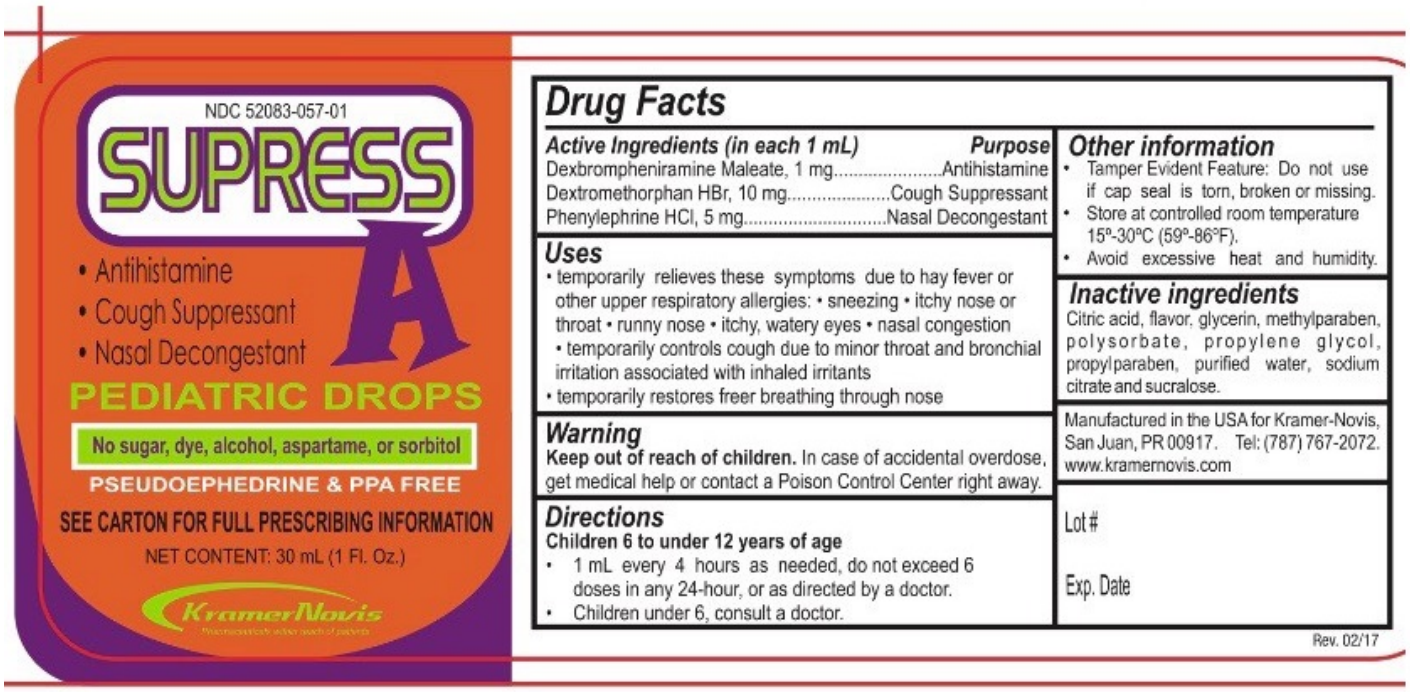
(787) 767-2072 / www.kramernovis.com

PRINCIPAL DISPLAY PANEL

OUTER LABEL



INNER LABEL



SUPRESS A
dexbromopheniramine maleate, dextromethorphan hbr, phenylephrine hcl syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-057
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	1 mg in 1 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE (GRAPE)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52083-057-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/01/2012	

Labeler - Kramer Novis (090158395)

Registrant - KRAMER NOVIS (090158395)

Revised: 12/2017 Kramer Novis