

SUPRESS DM- dextromethorphan hydrobromide, guaifenesin 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 DM

Drug Facts

Active Ingredients (in each 1 ml)

Dextromethorphan HBr, 5 mg

Guaifenesin, 50 mg

Purpose

Cough Suppressant

Expectorant

Uses

- Temporarily controls cough due to minor throat and bronchial irritation as may occur with a cold
- Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes, and make coughs more productive.

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 your child has

- 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 the recommended dosage.

Stop use and ask a doctor if

- new symptoms occur
- coughs persists for more than 1 week, tends to recur, 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

Inactive ingredients

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

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.

COUGH SUPPRESSANT

EXPECTORANT

No sugar, dye, alcohol, aspartame or sorbitol

DECONGESTANT FREE

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

www.kramernovis.com

Packaging

 <p>NDC 52083-058-01</p> <p>SUPRESS DM</p> <p>Cough Suppressant • Expectorant</p> <p>PEDIATRIC DROPS</p> <p>No sugar, dye, alcohol, aspartame, or sorbitol</p> <p>DECONGESTANT FREE</p> <p>SEE CARTON FOR FULL PRESCRIBING INFORMATION</p> <p>NET CONTENT: 30 mL (1 Fl. Oz.)</p> <p>KramerNovis Pharmaceuticals within reach of patients</p>	<p>Drug Facts</p> <table border="1"> <tr> <td> <p>Active Ingredients (in each 1 mL)</p> <p>Dextromethorphan HBr, 5 mg.....Cough Suppressant</p> <p>Guaifenesin, 50 mg.....Expectorant</p> </td> <td> <p>Purpose</p> </td> <td> <p>Other information</p> <ul style="list-style-type: none"> • 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. </td> </tr> <tr> <td colspan="2"> <p>Uses</p> <ul style="list-style-type: none"> • Temporarily controls cough due to minor throat and bronchial irritation as may occur with a cold • Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes, and make coughs more productive. </td> <td rowspan="2"> <p>Inactive ingredients</p> <p>Citric acid, flavor, glycerin, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate and sodium saccharin.</p> </td> </tr> <tr> <td colspan="2"> <p>Warning</p> <p>Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.</p> </td> </tr> <tr> <td colspan="2"> <p>Directions</p> <p>Children 6 to under 12 years of age</p> <ul style="list-style-type: none"> • 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. </td> <td> <p>Manufactured in the USA for Kramer-Novis, San Juan, PR 00917. Tel: (787) 767-2072. www.kramernovis.com</p> </td> </tr> </table>		<p>Active Ingredients (in each 1 mL)</p> <p>Dextromethorphan HBr, 5 mg.....Cough Suppressant</p> <p>Guaifenesin, 50 mg.....Expectorant</p>	<p>Purpose</p>	<p>Other information</p> <ul style="list-style-type: none"> • 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. 	<p>Uses</p> <ul style="list-style-type: none"> • Temporarily controls cough due to minor throat and bronchial irritation as may occur with a cold • Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes, and make coughs more productive. 		<p>Inactive ingredients</p> <p>Citric acid, flavor, glycerin, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate and sodium saccharin.</p>	<p>Warning</p> <p>Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.</p>		<p>Directions</p> <p>Children 6 to under 12 years of age</p> <ul style="list-style-type: none"> • 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. 		<p>Manufactured in the USA for Kramer-Novis, San Juan, PR 00917. Tel: (787) 767-2072. www.kramernovis.com</p>
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SUPRESS DM			
dextromethorphan hydrobromide, guaifenesin syrup			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-058

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

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (SWEET CHERRY)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-058-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/02/2013	

Labeler - KRAMER NOVIS (090158395)

Registrant - KRAMER NOVIS (090158395)