DESGEN DM- dextromethorphan hbr ,guaifenesin ,phenylephrine hcl solution
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.

DESGEN DM

Active ingredients (in each 5 mL tsp)

Dextromethorphan HBr, 10 mg

Guaifenesin, 100 mg

Phenylephrine HCL, 5mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Keep out of reach of children,In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Uses

• Suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants.
• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive
• temporarily relieves nasal congestion due to a cold

Warnings

Do not use if you are now 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have
• diabetes • heart disease • thyroid disease • high blood pressure • trouble urinating due to an enlarged prostate gland • cough that occurs with too much phlegm (mucus) • cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema.

When using this product do not use more than directed

Stop use and ask a doctor if
• you get nervous, dizzy, or sleepless
• symptoms do not get better within 7 days or are accompanied by fever
• coughs lasts more than 7 days, comes back, or is accompanied by fever, rash, or a persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Directions

Do not take more than 6 doses in any 24-hour period

Every 4 hours

Adult and Children 12 years of age and over	10 mL (2 tsp)
Children 6 to under 12 years of age	5 mL (1 tsp)
Children under 6 years of age	Consult physician

Inactive ingredients

Citric Acid, flavor, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate and sucralose.

Other Information

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

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

Packaging

DESGEN DM

dextromethorphan hbr ,guaifenesin ,phenylephrine hcl solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52083-646
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

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

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	grape	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52083-646-16	474 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/18/2014	

Labeler - Kramer Novis (090158395)

Registrant - Kramer Novis (090158395)