

PECGEN DMX- dextromethorphan hbr, guaifenesin in 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.

PECGEN® DMX

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextromethorphan HBr, 10 mg

Guaifenesin, 187 mg

Purposes

Antitussive

Expectorant

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.

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

- cough that occurs with too much phlegm (mucus)
- a 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

- 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.

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

Take every 4 hours, or as directed by a doctor.

Adults and children 12 years of age and older	Take two teaspoonfuls (10 mL). Do not exceed 8 teaspoonfuls in 24 hours
Children 6 to under 12 years of age	Take one teaspoonful (5 mL). Do not exceed 4 teaspoonfuls in 24 hours
Children 2 to under 6 years of age	Take 1/2 teaspoon (2.5 mL). Do not exceed 2 teaspoonfuls in 24 hours
Children under 2 years of age	DO NOT USE

Inactive ingredients

Citric acid, flavors, menthol, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium citrate, sucralose.

Other information

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

Questions or comments?

Call weekdays from 8 AM to 4 PM AST at **1-787-767-2072**. San Juan, PR 00917
www.kramernovis.com

Contains the same active ingredients as Trispec® DMX*

Sugar, Alcohol, Dye and Gluten **FREE**

CHERRY RASPBERRY FLAVOR

Manufactured in the USA for **Kramer Novis**

*Trispec® DMX is a registered trademark of Deliz Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Deliz Pharmaceutical Corp.

Packaging

NDC 52083-630-16

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 Guaifenesin, 187 mg.....Expectorant

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PECGEN[®] DMX

Contains the same active ingredients as Trispec[®] DMX*

**Dextromethorphan HBr
 ANTITUSSIVE
 Guaifenesin
 EXPECTORANT**

Sugar, Alcohol, Dye and Gluten FREE

CHERRY RASPBERRY FLAVOR

Net Content: 16 fl oz (473 mL)

Manufactured in the USA for



Drug Facts (continued)

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Lot No.
 Exp. Date

Rev. 06/19

PECGEN DMX

dextromethorphan hbr, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-630
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	187 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY, RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-630-16	474 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2015	

Labeler - KRAMER NOVIS (090158395)

Revised: 9/2019

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