

PECGEN DMX - guaifenesin, dextromethorphan hydrobromide 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.

DRUG FACTS

Active Ingredients/5 ml: guaifenesin 125 mg dextromethorphan hydrobromide 15 mg

Cough suppressant, expectorant

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive. restores free breathing.

suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants

Do not:

- use more than the recommended dose
- give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor.
- 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.
- 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.

Ask a doctor before use if you have

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.

Keep this and all medicines out of the reach of children

As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product

Inactives: Citric Acid, FDC Red 40, Flavor, Glycerin, Methylparaben, propylene Glycol, Propylparaben, Purified Water, Sodium Citrate, Sucralose

MM1

NDC 52083-620-16

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextromethorphan HBr, 15 mg..... *Purpose* Cough Suppressant

Guaifenesin, 125 mg..... Expectorant

Uses

- *helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus, drain bronchial tubes, and make coughs more productive
- *restores free breathing
- *suppresses cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants

Warnings

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- * 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.

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**COUGH SUPPRESSANT
EXPECTORANT**

Contains the same active ingredients as Trispec® DMX *

SUGAR FREE
ALCOHOL FREE
CHERRY FLAVOR

16 Fl.oz. (474 mL)



Drug Facts (continued)

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

do not take more than 4 doses in any 24-hour period

EVERY 6 HOURS	Adults 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 2 to under 6 years of age	2.5 mL (½ tsp)
	Children under 2 year of age	Consult physician

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.

Inactive Ingredients

Citric Acid, FD&C Red #40, Flavor, Glycerin, Methyl Paraben, Propyl Paraben, Propylene Glycol, Purified Water, Sodium Citrate, Sucralose.

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

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



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Directions Adults and Children 12 years of age and over 10 mL (2 tsp)
 Children 6 to under 12 years of age 5 mL (1 tsp) E V E R Y
 6 HOURS
 do not take more than 4 doses in any 24-hour period

PEGGEN DMX			
guaifenesin, dextromethorphan hydrobromide syrup			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-620
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	125 mg in 5 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL	
Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
GLYCERIN (UNII: PDC6A3C0OX)			
METHYL PARABEN (UNII: A2I8C7HI9T)			
PROPYL PARABEN (UNII: Z8IX2SC1OH)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			

SUCRALOSE (UNII: 96K6UQ3ZD4)

WATER (UNII: 059QF0KO0R)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-620-16	480 mL in 1 BOTTLE		

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)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(52083-620)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	repack(52083-620)

Revised: 2/2013

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