

PEGGEN PSE COUGH SUPPRESSANT EXPECTORANT NASAL DECONGESTANT GRAPE FLAVOR- dextromethorphan hydrobromide, guaifenesin, pseudoephedrine hydrochloride liquid
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.

PEGGEN® PSE COUGH SUPPRESSANT EXPECTORANT NASAL DECONGESTANT GRAPE FLAVOR

Drug Facts

Active Ingredients (in each 5 mL tsp)

Dextromethorphan HBr, USP 10 mg
Guaifenesin, USP 187 mg
Pseudoephedrine HCL, USP 30 mg

Purpose

Cough Suppressant
Expectorant
Nasal Decongestant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold or inhaled irritants
- helps loosen phlegm and thin bronchial secretions to make coughs more productive
- temporarily relieves nasal congestion

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 • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlarged prostate gland • 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 • nervousness, dizziness, or sleeplessness occur • 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

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

| | |
|---|---|
| Adults and children 12 years of age and older | 2 teaspoonfuls (10 mL) every 4 hours, not to exceed 8 teaspoonfuls in 24 hours or as directed by a doctor |
| Children 6 to under 12 years of age | 1 teaspoonful (5 mL) every 4 hours, not to exceed 4 teaspoonfuls in 24 hours or as directed by a doctor |
| Children 2 to under 6 years of age | Consult a doctor |

Other information

- Store at controlled room temperature 15°C-30°C (59°F-86°F)
- Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing

Inactive ingredients

Citric acid, grape flavor, methylparaben, monoammonium glycyrrhizinate, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sorbitol, sucralose

Contains the same active ingredients as Trispec[®] PSE

- SUGAR FREE • ALCOHOL FREE
- DYE FREE • GLUTEN FREE

GRAPE FLAVOR

Manufactured in the USA for Kramer Novis. San Juan, PR 00917.

Tel: (787) 767-2072 www.kramernovis.com

*** Trispec[®] PSE is a Registered Trademark of Deliz Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Deliz Pharmaceutical Corp.**

Packaging

NDC 52083-628-16

PEGGEN[®] PSE

Contains the same active ingredients
as Trispec[®] PSE

COUGH SUPPRESSANT EXPECTORANT NASAL DECONGESTANT

Dextromethorphan HBr 10 mg
Guaifenesin 187 mg
Pseudoephedrine HCl 30 mg

- SUGAR FREE • ALCOHOL FREE
- DYE FREE • GLUTEN FREE

GRAPE FLAVOR
16 Fl.oz. (473 mL)



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(in each 5 mL tsp)

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| Guaifenesin, USP 187 mg | | Expectorant |
| Pseudoephedrine HCl, USP 30 mg | | Nasal Decongestant |

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Rev 07/18

PEGGEN PSE COUGH SUPPRESSANT EXPECTORANT NASAL DECONGESTANT GRAPE FLAVOR

dextromethorphan hydrobromide, guaifenesin, pseudoephedrine hydrochloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52083-628 |
| 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 |
| PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 30 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| METHYLPARABEN (UNII: A2I8C7H9T) | |
| AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C) | |
| POTASSIUM CITRATE (UNII: EE90ONI6FF) | |

| | |
|---|--|
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |

Product Characteristics

| | | | |
|-----------------|----------------------|---------------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | GRAPE (Grape Flavor) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:52083-628-16 | 474 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/08/2014 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 08/08/2014 | |

Labeler - Kramer Novis (090158395)