

**TRISPEC PSE COUGH SUPPRESSANT EXPECTORANT NASAL DECONGESTANT  
GRAPE FLAVOR- dextromethorphan hydrobromide, guaifenesin,  
pseudoephedrine hydrochloride liquid  
Deliz Pharmaceutical Corp**

*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.*

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**TRISPEC PSE Cough Suppressant Expectorant Nasal Decongestant GRAPE  
Flavor**

**Drug Facts**

**Active ingredients (in each 5 mL teaspoonful)**

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
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by excessive phlegm (mucus)

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**When using this product**

- **do not exceed recommended dosage**

**Stop use and ask a doctor if**

- cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.
- symptoms do not improve within 7 days or are accompanied by fever
- nervousness, dizziness, or sleeplessness occur

**If pregnant or breastfeeding**

ask a health professional before use

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- use only with enclosed measuring cup
- do not use enclosed measuring cup for any other drug product

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Adults and children 12 years of age and older:	2 teaspoonfuls (tsp) 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 (tsp) 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:	½ teaspoonful (tsp) every 4 hours not to exceed 2 teaspoonfuls in 24 hours, or as directed by a doctor.

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**Other Information**

- Store at room temperature 15°C-30°C (59°F-86°F)

**Inactive ingredients**

Bitter Mask, Citric Acid, Glycerin, Grape Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol

**Questions?**

Call 1-787-701-3312. You may also report serious side effects to this phone number.

## Product Labels

Lot #  
Exp date:

NDC 58238-228-04



**TRISPEC  
PSE**

**Cough Suppressant  
Expectorant  
Nasal Decongestant**



**4 fl oz (118 ml)**

**Grape Flavor**

**Sugar  
Alcohol  
Dye  
Gluten  
Free**

**TAMPER EVIDENT:** Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

**Deltiz**  
Pharmaceutical

Distributed by Deltiz Pharmaceutical Corp.  
Carolina, PR 00979



N 58238-228-04 9

**Drug Facts**

**Active ingredients**  
(in each 5 mL teaspoonful)  
Dextromethorphan HBr, USP 10 mg .. Cough suppressant  
Guaifenesin, USP 187 mg ..... Expectorant  
Pseudoephedrine HCl, USP 30 mg ..... Nasal decongestant

**Purpose**  
Cough suppressant and expectorant with 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

Lift Here for more **Drug Facts** ▲

**Drug Facts (continued)**

**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 ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough accompanied by excessive phlegm (mucus)

**When using this product** ■ do not exceed recommended dosage

**Stop use and ask a doctor if** ■ cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition. ■ symptoms do not improve within 7 days or are accompanied by fever ■ nervousness, dizziness, or sleeplessness occur

**If pregnant or breastfeeding** ask a health professional before use.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Drug Facts (continued)**

**Directions**  
■ use only with enclosed measuring cup  
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**Drug Facts (continued)**

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■ Store at room temperature 15°C-30°C (59°F-86°F)

**Inactive ingredients**  
Bitter Mask, Citric Acid, Glycerin, Grape Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol

**Questions?** Call 1-787-701-3312. You may also report serious side effects to this phone number.

## TRISPEC PSE COUGH SUPPRESSANT EXPECTORANT NASAL DECONGESTANT GRAPE FLAVOR

dextromethorphan hydrobromide, guaifenesin, pseudoephedrine hydrochloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58238-228
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Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	187 mg in 5 mL
<b>PSEUDOEPHEDRINE HYDROCHLORIDE</b> (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE (Grape Flavor)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58238-228-04	1 in 1 CARTON	03/20/2015	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/20/2015	

**Labeler** - Deliz Pharmaceutical Corp (826391138)

### Establishment

Name	Address	ID/FEI	Business Operations
Woodfield Pharmaceutical, LLC		079398730	manufacture(58238-228)

