

TRISPEC PSE PEDIATRIC DROPS 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.

TRISPEC PSE Pediatric Drops Cough Suppressant Expectorant Nasal Decongestant GRAPE Flavor

Drug Facts

Active ingredients (in each 5 mL)

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 (mucus) 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

- 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

Keep out of reach of children.

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

Directions

- For children under 6 years of age, use enclosed dropper
- do not use enclosed dropper for any other drug product

Children 2 to under 6 years of age:	2½ mL every 4 hours not to exceed 10 mL in 24 hours, or as directed by a doctor.
Children under 2 years of age:	Consult a doctor.

Other information

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

Inactive ingredients

Bitter Mask, Citric Acid Anhydrous, 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 Pediatric Drops Cough Suppressant Expectorant Nasal Decongestant GRAPE Flavor 2oz/59ml (58238-230-02)

Lot No:
Exp. Date:

NDC 58238-230-02

**TRISPEC
PSE**

Pediatric Drops

Cough Suppressant
Expectorant
Nasal Decongestant

Sugar
Alcohol
Dye
Gluten
Free

2 fl oz (59ml)

Grape Flavor

Delix
pharmaceutical

Distributed by Delix Pharmaceutical Corp.
Carolina, PR 00979

Drug Facts

Active ingredients (in each 5 mL) Purpose

Dextromethorphan HBr, USP
10 mg Cough suppressant
Guaifenesin, USP 187 mg Expectorant
Pseudoephedrine HCl, USP
30 mg Nasal decongestant

Lift Here for
Drug Facts

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



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Drug Facts (continued)

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Rev. 08/14

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dextromethorphan hydrobromide, guaifenesin, pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58238-230
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

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:58238-230-02	1 in 1 CARTON	02/27/2014	
1		60 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	02/27/2014	

Labeler - Deliz Pharmaceutical Corp (826391138)

Establishment

Name	Address	ID/FEI	Business Operations
Woodfield Pharmaceutical, LLC		079398730	manufacture(58238-230)