

TRISPEC DMX PEDIATRIC DROPS COUGH SUPPRESSANT EXPECTORANT CHERRY RASPBERRY FLAVOR- dextromethorphan hydrobromide, guaifenesin 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 DMX Pediatric Drops Cough Suppressant Expectorant CHERRY RASPBERRY Flavor

TRISPEC DMX Pediatric Drops Cough Suppressant Expectorant CHERRY RASPBERRY Flavor

Active ingredients (in each 5 mL teaspoonful)

Dextromethorphan HBr, USP 10 mg
Guaifenesin, USP 187 mg

Purpose

Cough suppressant
Expectorant

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

Warnings

Do not use

in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

Ask a doctor before use if the child has

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

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.

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:	2.5 mL every 4 hours not to exceed 15 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

cherry flavor, citric acid, glycerin, methylparaben, monoammonium glycyrrhizinate, potassium citrate, potassium sorbate, propylparaben, propylene glycol, purified water, raspberry flavor, sorbitol, sucralose

Questions?

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

TRISPEC DMX Pediatric Drops Cough Suppressant Expectorant CHERRY RASPBERRY Flavor 2oz/60ml (58238-229-02)

NDC 58238-229-02

**TRISPEC
DMX**

Pediatric Drops
**Cough Suppressant
Expectorant**



Sugar
Alcohol
Dye
Gluten
Free

2 fl oz (60 ml)

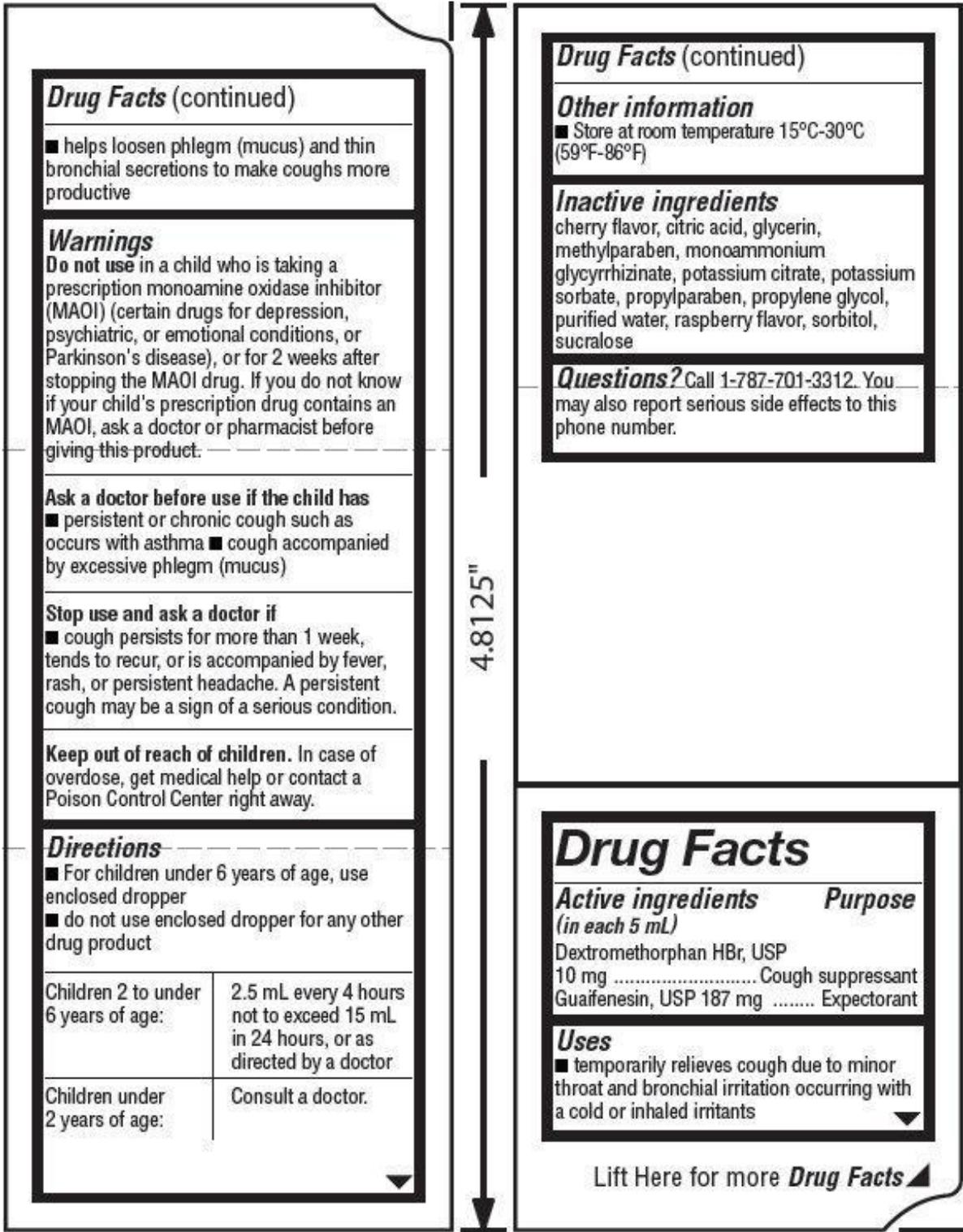
Cherry Raspberry Flavor

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

Distributed by **Deliz** Pharmaceutical Corp.,
Carolina, PR 00979



N 3 58238-229-02 2



TRISPEC DMX PEDIATRIC DROPS COUGH SUPPRESSANT EXPECTORANT CHERRY RASPBERRY FLAVOR

dextromethorphan hydrobromide, guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58238-229
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY, RASPBERRY (Cherry Raspberry Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58238-229-02	1 in 1 PACKAGE		
1		60 mL in 1 BOTTLE		

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
TG United Liquid, Inc.		830980947	manufacture(58238-229)

