## TRISPEC DMX COUGH SUPPRESSANT EXPECTORANT PEACH FLAVORdextromethorphan 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.

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## TRISPEC DMX Cough Suppressant Expectorant Peach Flavor

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## 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 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

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- 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.

**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 Poison Control Center right away.

#### **Directions**

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

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.

#### Other Information

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

## **Inactive Ingredients**

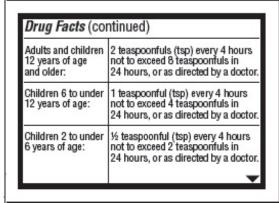
Bitter Mask, Citric Acid, Maltitol, Peach Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sorbitol, Sucralose

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

TRISPEC DMX COUGH SUPPRESSANT EXPECTORANT PEACH FLAVOR 4 OZ/118 ML (58238-227-04)



## 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product. Ask a doctor before use if you have persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema cough accompanied by excessive phlegm (mucus) Stop use and ask a doctor if a 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. If pregnant or breastfeeding ask a health professional Keep out of reach of children. In case of overdose, get medical help or contact Poison Control Center right away Directions ■use only with enclosed measuring cup do not use enclosed measuring cup for any other drug



## Drug Facts (continued)

#### Other Information

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

#### Inactive Ingredients

Bitter Mask, Citric Acid, Maltitol, Peach Flavor, Propylene Glycol, Purified Water, Sodium Citrate, Sorbitol, Sucralose

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# TRISPEC DMX COUGH SUPPRESSANT EXPECTORANT PEACH FLAVOR

dextromethorphan hydrobromide, guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58238-227
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
	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)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
MALTITOL (UNII: D65DG142WK)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	PEACH	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58238-227- 04	1 in 1 PACKAGE	11/18/2014		
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	11/18/2014	

## Labeler - Deliz Pharmaceutical Corp (826391138)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Woodfield Pharmaceutical, LLC		079398730	manufacture(58238-227)	

Revised: 11/2021 Deliz Pharmaceutical Corp