

**DELTUSS DMX COUGH SUPPRESSANT NASAL DECONGESTANT ANTIHISTAMINE GRAPE FLAVOR- dexchlorpheniramine maleate, dextromethorphan hydrobromide, 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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**DELTUSS DMX Cough Suppressant Nasal Decongestant Antihistamine GRAPE Flavor**

**Drug Facts**

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

Dexchlorpheniramine maleate, USP 1 mg  
Dextromethorphan HBr, USP 15 mg  
Pseudoephedrine HCl, USP 30 mg

**Purpose**

Antihistamine

Cough suppressant

Nasal Decongestant

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold or inhaled irritants
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- Temporarily relieves these symptoms due to hay fever (allergic rhinitis):
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- Temporarily restores freer breathing through the nose

**Warnings**

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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough accompanied by excessive phlegm (mucus)

### **Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers**

### **When using this product**

- **do not exceed recommended dosage**
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery
- excitability may occur especially in children

### **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

Adults and children 12 years of age and older:	2 teaspoonfuls (tsp) every 6 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 6 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 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.

### **Product Labels**

NDC 58238-225-04

**DELTUSS<sup>®</sup>**  
**DMX**

**Cough Suppressant  
Nasal Decongestant  
Antihistamine**

**4 fl oz (118 mL)**

**Grape Flavor**

**Sugar  
Alcohol  
Dye  
Gluten  
Free**

Lot No:  
Exp. Date:

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

Distributed by Delitz Pharmaceutical Corp.  
Carolina, PR 00979



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## Drug Facts

### Active ingredients

(in each 5 mL teaspoonful)

Dexchlorpheniramine Maleate USP 1 mg .. Antihistamine  
Dextromethorphan HBr, USP 15 mg .. Cough suppressant  
Pseudoephedrine HCl, USP 30 mg .. Nasal decongestant

### Purpose

**Uses** ■ Temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold or inhaled irritants ■ Temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies

Lift Here for more **Drug Facts**

### Drug Facts (continued)

■ Temporarily relieves these symptoms due to hay fever (allergic rhinitis): ■ Runny nose ■ sneezing  
■ itching of the nose or throat ■ itchy, watery eyes  
■ Temporarily restores freer breathing through the nose

### 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  
■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ difficulty in urination due to enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema  
■ cough accompanied by excessive phlegm (mucus)

**Ask a doctor or pharmacist before use if you are taking sedatives of tranquilizers.**

**When using this product** ■ do not exceed recommended dosage ■ marked drowsiness may occur  
■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect ■ avoid alcoholic beverages  
■ use caution when driving a motor vehicle or operating machinery ■ excitability may occur especially in children

**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

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### Other information

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## DELTUSS DMX COUGH SUPPRESSANT NASAL DECONGESTANT ANTIHISTAMINE GRAPE FLAVOR

dexchlorpheniramine maleate, dextromethorphan hydrobromide, pseudoephedrine hydrochloride liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58238-225
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>DEXCHLORPHENIRAMINE MALEATE</b> (UNII: B10YD955QW) (DEXCHLORPHENIRAMINE - UNII:3Q9Q0B929N)	DEXCHLORPHENIRAMINE MALEATE	1 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 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>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### 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:58238-225-04	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(58238-225)