

**POLY-HIST DM- dextromethorphan hydrobromide, phenylephrine hcl and thonzylamine hcl liquid**  
**Poly Pharmaceuticals, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**Poly-Hist DM Liquid**

**Drug Facts**

***Active ingredients***

**(in each 5 mL teaspoonful)**

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Thonzylamine HCl 25 mg

***Purpose***

Antitussive

Nasal Decongestant

Antihistamine

***Uses***

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies:

- cough due to minor throat and bronchial irritation
- runny nose
- sneezing
- itching of the nose and throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages

***Warnings***

**Do not exceed recommended dosage.**

**Do not use this product**

- 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**

- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- heart disease
- high blood pressure
- thyroid disease
- diabetes

**Ask a doctor or pharmacist before use if**

**you are** taking sedatives or tranquilizers.

**When using this product**

- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- use caution when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if:**

- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.
- nervousness, dizziness, or sleeplessness occur
- new symptoms occur

**If pregnant or breast feeding,**

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****Do not exceed recommended dosage.**

Adults and children 12 years of age and over:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours, or as directed by a doctor.
Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 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 59 °- 86 °F (15 ° - 30 °C)

### ***Inactive ingredients***

Bubblegum Flavor, Citric Acid, Magnasweet, Methyl Paraben, Potassium Citrate, Potassium Sorbate, Propyl Paraben, Propylene Glycol, Purified Water, Sorbitol, Sucralose.

### ***Questions? Comments?***

Serious side effects associated with use of this product may be reported to this number. Call 1-800-882-1041 Mon. - Fri. (8 a.m. to 5 p.m. CST).

### **PRINCIPAL DISPLAY PANEL**

NDC 50991-220-16

Poly-Hist DM Liquid

Antitussive • Nasal Decongestant

Antihistamine

Bubblegum Flavor

16 fl oz (473 mL)

NDC 50991-220-16

**Poly-Hist DM**  
*New Formula*  
**Liquid**

**Antitussive • Nasal Decongestant  
 Antihistamine**

Each 5 mL (1 teaspoonful) contains:  
 Dextromethorphan HBr ..... 10 mg  
 Phenylephrine HCl ..... 5 mg  
 Thonzylamine HCl ..... 25 mg

**Bubblegum Flavor**

**SUGAR FREE / ALCOHOL FREE  
 DYE FREE / GLUTEN FREE**

Distributed by:  
 Poly Pharmaceuticals  
 Huntsville, AL 35763

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



**Drug Facts**

**Active ingredients (in each 5 mL teaspoonful)**  
 Dextromethorphan Hydrobromide 10 mg ..... Antitussive  
 Phenylephrine HCl 5 mg ..... Nasal Decongestant  
 Thonzylamine HCl 25 mg ..... Antihistamine

**Purpose**

**Uses:** temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper respiratory allergies: ■ cough due to minor throat and bronchial irritation ■ runny nose ■ sneezing ■ itching of nose or throat ■ itchy, watery eyes ■ nasal congestion ■ reduces swelling of nasal passages

**Warnings**

Do not exceed recommended dosage.

Do not use this product

■ 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

■ a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema ■ a cough that occurs with too much phlegm (mucus) ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes

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

When using this product

■ excitability may occur, especially in children  
 ■ may cause marked drowsiness  
 ■ avoid alcoholic drinks  
 ■ alcohol, sedatives, and tranquilizers may increase the drowsiness effect

**Drug Facts (continued)**

■ use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

■ cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.

■ nervousness, dizziness, or sleeplessness occur  
 ■ new symptoms occur

If pregnant or breast-feeding, 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**

Do not exceed recommended dosage.

Adults and children 12 years of age and over: 2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours, or as directed by a doctor.

Children 6 to under 12 years of age: 1 teaspoonful (5 mL) every 4 hours, not to exceed 6 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 59° - 86°F (15° - 30°C)

**Inactive ingredients**

Bubble Gum Flavor, Citric Acid Anhydrous, Glycerin, Propylene Glycol, Purified Water, Sodium Benzoate, Sodium Citrate Dihydrate, Sorbitol, Sucralose.

**Questions? Comments?**

Serious side effects associated with use of this product may be reported to this number. Call 1-800-882-1041 Mon. - Fri. (8 a.m. to 5 p.m. CST).

Rev. 10/17

**POLY-HIST DM**

dextromethorphan hydrobromide, phenylephrine hcl and thonzylamine hcl liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50991-220
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL
<b>THONZYLAMINE HYDROCHLORIDE</b> (UNII: 6K9YKD48Y4) (THONZYLAMINE - UNII:R79646H5Z8)	THONZYLAMINE HYDROCHLORIDE	25 mg in 5 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	

<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	BUBBLE GUM	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-220-15	6 in 1 TRAY	06/22/2013	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:50991-220-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/22/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/22/2013	

**Labeler** - Poly Pharmaceuticals, Inc. (198449894)

Revised: 1/2024

Poly Pharmaceuticals, Inc.