

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

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

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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?

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Rev. 10/17

POLY-HIST DM

dextromethorphan hydrobromide, phenylephrine hcl and thonzylamine hcl liquid

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

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
OTC Monograph Drug	M012	06/22/2013	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 7/2024

Poly Pharmaceuticals, Inc.