POLYTUSSIN DM- dextromethorphan hbr, phenylephrine hcl, pyrilamine maleate syrup
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.

Polytussin DM

Active ingredients

(in each 5 mL teaspoonful)

Dextromethorphan HBr..... 7.5 mg
Phenylephrine HCl..... 5 mg
Pyrilamine Maleate..... 12.5 mg

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

Uses

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

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

Warnings

Do not exceed recommended dosage.

Ask a doctor before use if you have

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

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
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- 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.
- new symptoms 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

Adults 12 and over: 10 mL every 4 hours

Not to exceed 60 mL in 24hours

Children 6-12: 5 mL every 4 hours,

Not to exceed 30 mL in 24hrs

Children 2-6: Consult a doctor

Other information

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

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).

Inactive ingredients

Citric Acid, Flavor, Methylparaben, Potassium Citrate, Propylene Glycol, Propylparaben, Purified water, Sucralose,Sorbitol

Antihistamine

Cough Suppressant

Nasal Decongestant

POLYTUSSIN DM

dextromethorphan hbr, phenylephrine hcl, pyrilamine maleate syrup

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50991-132
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 5 mL
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	12.5 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	COTTON CANDY (clear, colorless)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-132-16	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	
2	NDC:50991-132-15	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/08/2023	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 1/2024 Poly Pharmaceuticals, Inc.