

POLY-VENT DM- dextromethorphan hbr, guaifenesin and pseudoephedrine hcl tablet

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.

Poly-Vent DM Tablets

Drug Facts

Active ingredients

Dextromethorphan HBr 20mg

Guaifenesin 380mg

Pseudoephedrine HCl 60mg

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

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 associated with a cold
- alleviates cough to help you sleep
- non-narcotic cough suppressant for relief of cough
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- itchy, watery eyes
- nasal congestion
- runny nose
- sneezing
- itching of the nose and throat

Warnings

- **Do not exceed recommended dosage.**
- a persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.

Ask a doctor or pharmacist before 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:

- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or where cough is accompanied by excessive phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

Stop use and ask a doctor if:

- nervousness, dizziness, or sleeplessness 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

Adults and children 12 years of age and over:	1 tablet every 4 hours, not to exceed 4 tablets in 24 hours, or as directed by a doctor.
Children age 6 to under 12 years of age:	½ tablet every 4 hours, not to exceed 2 tablets in 24 hours, or as directed by a doctor.
Children 2 to under 6 years of age:	Consult a doctor.

Other information

Tamper evident: do not use if tamper evident seal is broken or missing. Store at 15°-30°C (59°-86°F).

Poly Vent DM is a yellow, oblong, capsule shaped, scored tablet, debossed POLY 214 on one side and blank on the other.

Inactive ingredients

FD&C Yellow #5, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate.

Questions? Comments?

Call 1-800-882-1041.

Manufactured for:

Poly Pharmaceuticals

Quitman, MS 39355

(800) 882-1041 Rev. 04/13

PRINCIPAL DISPLAY PANEL

NDC 50991-214-01

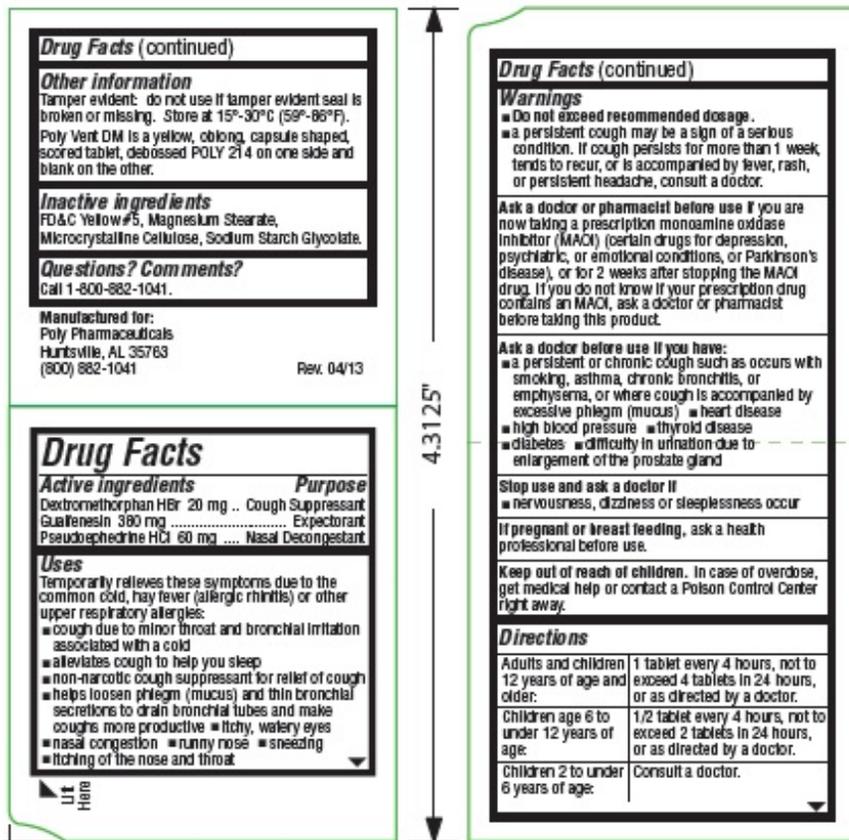
Poly-Vent DM Tablets

Cough Suppressant

Expectorant ● Nasal Decongestant

100 tablets





POLY-VENT DM

dextromethorphan hbr, guaifenesin and pseudoephedrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50991-214
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	380 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	yellow	Score	2 pieces
Shape	CAPSULE (Oblong)	Size	19mm
Flavor		Imprint Code	POLY214
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-214-02	12 in 1 CARTON	06/17/2013	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:50991-214-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/17/2013	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 1/2024

Poly Pharmaceuticals, Inc.