

POLY-VENT IR- guaifenesin and pseudoephedrine hcl tablet
Poly Pharmaceuticals, Inc.

Poly-Vent IR Tablets

Drug Facts

Active ingredients

(in each tablet)

Guaifenesin 380mg

Pseudoephedrine HCl 60 mg

Purpose

Expectorant

Nasal Decongestant

Uses

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

- helps loosen phlegm and thin bronchial secretions to make coughs more productive
- nasal congestion
- runny nose
- sneezing
- itching of the nose and throat
- itchy, watery eyes

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.

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

- a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or if cough is accompanied by excessive phlegm
- 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 IR Tablets are a blue, oval, scored tablet debossed POLY 212 on one side, plain on the other.

Inactive ingredients

FD&C Blue #2, 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

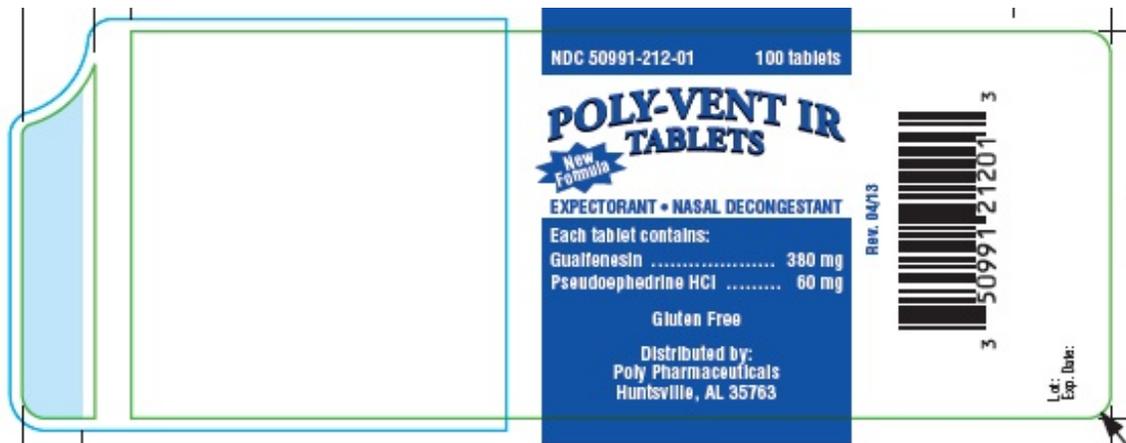
PRINCIPAL DISPLAY PANEL

NDC 50991-212-01

Poly-Vent IR Tablets

Expectorant ● Nasal Decongestant

100 tablets



Drug Facts (continued)

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Manufactured for:
 Poly Pharmaceuticals
 Huntsville, AL 35763
 (800) 882-1041

Rev. 04/13

4.3125"

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 ■ 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 older:	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:	1/2 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.

POLY-VENT IR

guaifenesin and pseudoephedrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50991-212
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	380 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	blue	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	POLY212
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-212-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/11/2013	
2	NDC:50991-212-02	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/11/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/11/2013	

Labeler - Poly Pharmaceuticals, Inc. (198449894)