

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

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**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

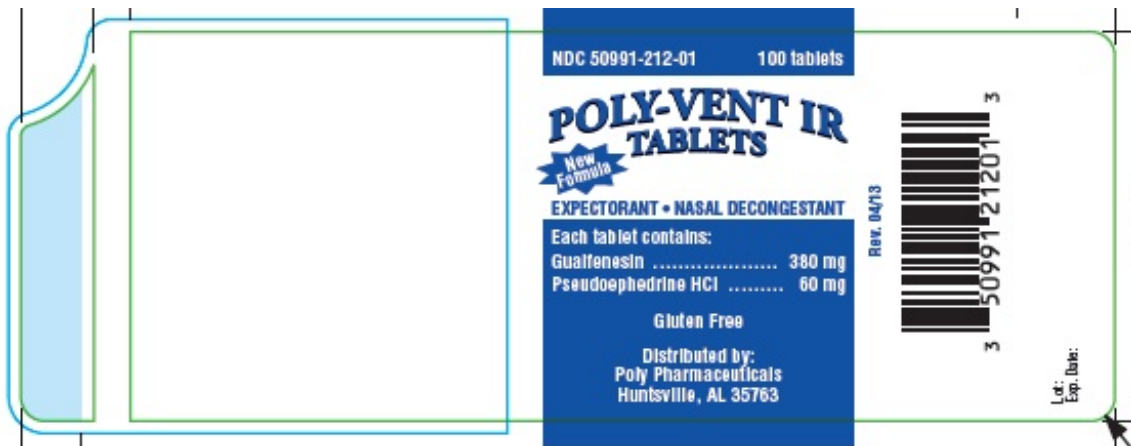
**PRINCIPAL DISPLAY PANEL**

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"

**Drug Facts**

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Pseudoephedrine HCl 60 mg	Nasal Decongestant

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

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**Drug Facts (continued)**

■ 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 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.

guaifenesin and pseudoephedrine hcl tablet

**Product Information**

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

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	POLY212
<b>Contains</b>			

**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)