

**POLY-TUSSIN AC- brompheniramine maleate, codeine phosphate,  
phenylephrine hydrochloride liquid  
Poly Pharmaceuticals, Inc.**

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**Poly-Tussin AC**

**Active ingredients  
(in each 5 mL teaspoonful)**

Brompheniramine Maleate 4 mg  
Codeine Phosphate 10 mg  
Phenylephrine Hydrochloride 10 mg

**Purpose**

Antihistamine  
Antitussive  
Decongestant

**Uses**

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

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

**Ask a doctor before use if you have**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to the enlargement of the 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

- a chronic pulmonary disease or shortness of breath, or children who are taking other drugs
- 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
- may cause or aggravate constipation
- alcohol, sedatives, and tranquilizers may increase drowsiness
- 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. These could be signs of a serious condition.
- new symptoms occur

**If pregnant or breast-feeding,**

**ask a health professional before use.**

**Keep out of the 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 over 12 years of age:	1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 6 teaspoonfuls in a 24 hour period.
Children 6 to under 12 years of age:	1/2 teaspoonful (2.5 mL) every 4 to 6 hours, not to exceed 3 teaspoonfuls in a 24 hour period.
Children under 6 years of age:	Not recommended for use.

## **Other information**

Store at 59° - 86°F(15° - 30°C)

## **Inactive ingredients**

Bubble gum flavor, citric acid, methylparaben, potassium citrate, potassium sorbate, propylparaben, propylene glycol, purified water, raspberry flavor, 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 (8a.m. to 5 p.m. CST)

## **Product Packaging:**

Packaging below represents label currently used:

Principal display panel and side panel for 473 mL label:

**NDC 50991-723-16**

## **POLY-TUSSIN AC LIQUID**

**Antihistamine/Antitussive/Decongestant**

**Alcohol Free/Dye Free**

### **NEW FORMULA**

Each 5 mL (1 teaspoonful) contains:

Brompheniramine Maleate.....	4 mg
Codeine Phosphate.....	10 mg
Phenylephrine HCl.....	10 mg

## **Raspberry-Bubble Gum Flavor**

**CV**

**Rx Only**

**Distributed by:**

**Poly Pharmaceuticals**

**Huntsville, AL 35763**

16 fl oz. (473 mL)

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Dispense in a tight, light-resistant container with a child-resistant closure.

This bottle is not to be dispensed to consumer.

NDC 50991-723-16

## POLY-TUSSIN AC LIQUID

Antihistamine • Antitussive  
Nasal Decongestant  
Alcohol Free • Dye Free


Each 5 mL (1 teaspoonful) contains:  
Brompheniramine Maleate ..... 4 mg  
Codeine Phosphate ..... 10 mg  
Phenylephrine HCl ..... 10 mg

Raspberry-Bubble Gum Flavor



Distributed by:  
Poly Pharmaceuticals  
Huntsville, AL 35763

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.



16 fl oz. (473 mL)

### Drug Facts

**Active ingredients (in each 5 mL teaspoonful)**

Brompheniramine Maleate 4 mg	Antihistamine
Codeine Phosphate 10 mg	Antitussive
Phenylephrine Hydrochloride 10 mg	Nasal Decongestant

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

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of the 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 breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to the enlargement of the 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
- a chronic pulmonary disease or shortness of breath, or children who are taking other drugs
- 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
- may cause or aggravate constipation
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

### Drug Facts (continued)

**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. These could be signs of a serious condition.
- new symptoms occur

**If pregnant or breast-feeding, ask a health professional before use.**

**Keep out of the reach of children.**

**In case of overdose, get medical help or contact a Poison Control Center right away.**

**Directions**

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Adults and children over 12 years of age:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in a 24 hour period.
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Iss. 01/14

## POLY-TUSSIN AC

brompheniramine maleate, codeine phosphate, phenylephrine hydrochloride liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50991-723
Route of Administration	ORAL	DEA Schedule	CV

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BROMPHENIRAMINE MALEATE</b> (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	4 mg in 5 mL
<b>CODEINE PHOSPHATE</b> (UNII: G5L05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	RASPBERRY, BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-723-15	12 in 1 TRAY	06/02/2014	
1		15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:50991-723-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/02/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/02/2014	

Labeler

- Poly Pharmaceuticals, Inc. (198449894)