POLY-TUSSIN AC- brompheniramine maleate, codeine phosphate, phenylephrine hydrochloride liquid
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-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

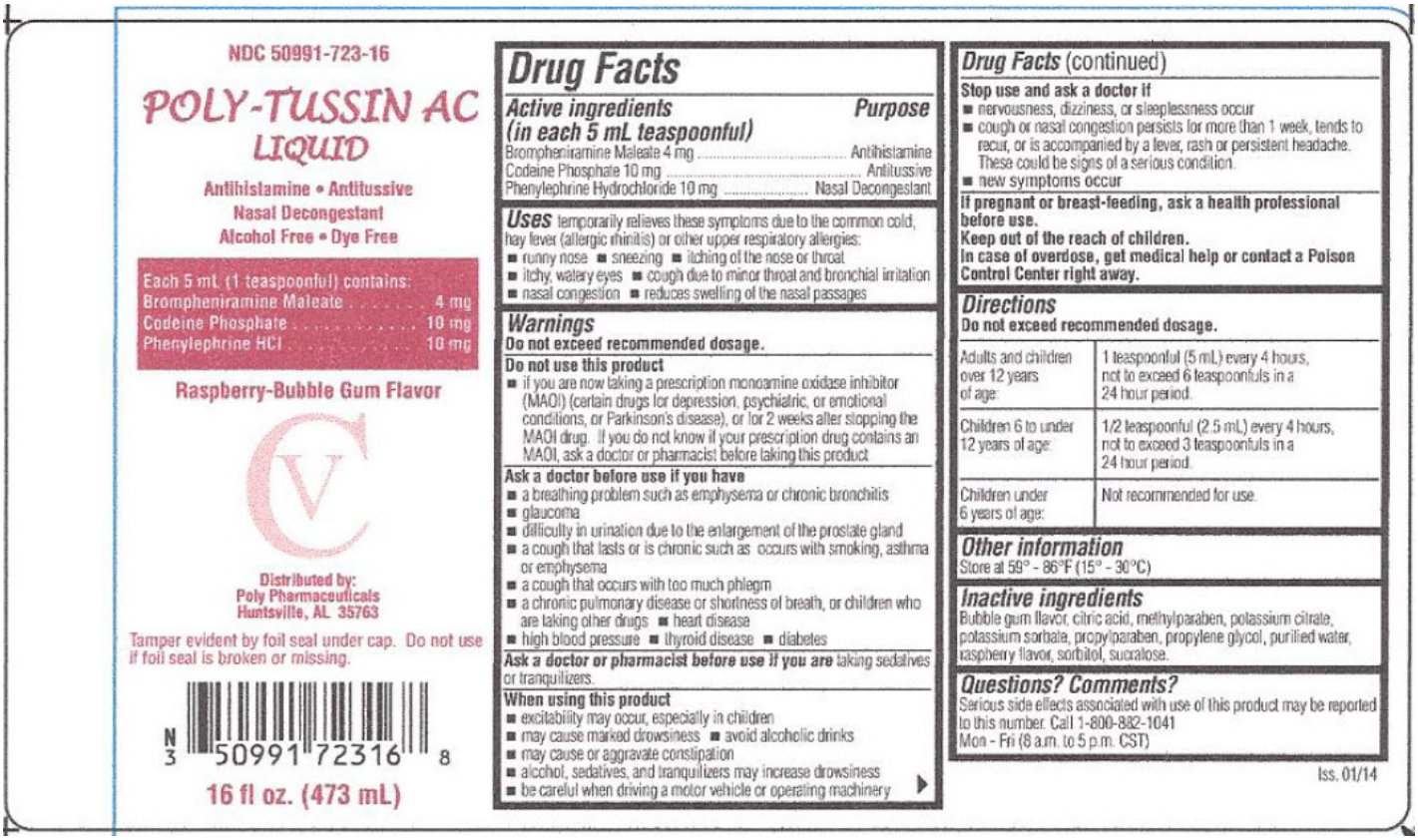
Distributed by:
Poly Pharmaceuticals
Huntsville, AL 35763

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.



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**
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	4 mg in 5 mL
CODEINE PHOSPHATE (UNII: GSL05Y1MN6) (CODEINE ANHYDROUS - UNII:UX6OWY2V7J)	CODEINE PHOSPHATE	10 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (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
unapproved drug other		06/02/2014	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Revised: 1/2024 Poly Pharmaceuticals, Inc.