

BIO T PRES-B - brompheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Advanced Generic Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients (in each 5 mL tsp)	Purpose
Brompheniramine maleate 1 mg	Antihistamine
Dextromethorphan HBr 5 mg	Cough Suppressant
Phenylephrine HCl 2.5 mg	Nasal Decongestant

Uses

- temporarily relieves symptoms due to hay fever or other upper respiratory allergies:
 - sneezing
 - itchy nose or throat
 - runny nose
 - itchy, water eyes
 - nasal congestion
- temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants
- temporarily restores freer breathing through nose

Warnings

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. Do not use on a child under 2 years of age.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- glaucoma
- diabetes
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or a pharmacist before

- giving this product to children who are taking sedatives or tranquilizers
- if you are taking sedatives or tranquilizers

Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, without first consulting the child's doctor.

When using this product

- **do not use more than directed**
- may cause drowsiness
- avoid alcoholic drink
- alcohol, sedatives and tranquilizers may increase drowsiness effect
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- you get nervous, dizzy or sleeplessness
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

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

Directions Do not exceed more than 6 doses in any 24-hour period.

adults and children 12 years of age and over	take 1 teaspoonfuls (5 mL) every 4 hours
children 6 to under 12 years of age	take 1/2 teaspoonfuls (2.5mL) every 4 hours
children 2 years to under 6 years of age	ask a doctor
children under 2 years of age	do not use

Other Information

- Store between 15-30 degrees C (59-89 degrees F)
- Tamper evident feature: Do not use if cap seal is broken or missing

Inactive Ingredients

Water, citric acid, methylparaben, glycerin, propylene glycol, propylparaben, sodium citrate, flavor, sucralose

Questions or comments: 1-305-403-3788

Advanced Generic Corporation, Miami, Fl 33166

www.advancedgeneric.com

Drugs Facts

Active Ingredients (in each 5 mL tsp)	Purpose
Brompheniramine Maleate, 4 mg	Antihistamine
Dextromethorphan HBr, 20 mg	Cough Suppressant
Phenylephrine HCl, 10 mg	Nasal Decongestant

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: sneezing, itchy nose or throat, runny nose, itchy, watery eyes, nasal congestion • temporarily controls cough due to minor throat and bronchial irritation associated with inhaled irritants • temporarily restores freer breathing through nose

Ask a doctor before use if you have

heart disease • high blood pressure • thyroid disease • glaucoma • diabetes • cough that occurs with too much phlegm (mucus) • trouble urinating due to an enlarged prostate gland • a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

Warnings

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 that contains an MAOI, ask a doctor or pharmacist before taking this product. Do not use in a child under 2 years of age.

Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, without first consulting the child's doctor.

Ask a doctor or a pharmacist before

giving this product to children who are taking sedatives or tranquilizers • If you are taking sedatives or tranquilizers

When using this product

do not use more than directed • may cause drowsiness • avoid alcoholic drinks

Tussi Pres® is a registered trademark of Kramer Novis. This product is not manufactured, distributed or marketed by Kramer Novis.

Lot #:

Exp. Date:

NDC 45737-226-16

BIO T PRES-B

- Antihistamine
- Cough Suppressant
- Nasal Decongestant

Sugar FREE • Dye FREE
Alcohol FREE • Saccharin FREE

Contains the same active ingredients as
Tussi Pres®-B₊

Grape Flavor

Manufactured For:



advanced generic corporation
Miami, FL 33166
www.advancedgeneric.com

16 fl. oz. (473 mL)

Drugs Facts (Continued)**Warnings (Continued)**

alcohol, sedatives, and tranquilizers may increase drowsiness effect • be careful when driving a motor vehicle or operating machinery • excitability may occur, especially in children.

Stop use and ask a doctor if

you get nervous, dizzy, or sleepless • symptoms do not get better within 7 days or are accompanied by fever • cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions Do not exceed more than 6 doses in any 24-hour period.

adults and children 12 years of age and over	take 1 teaspoonful (5 mL) every 4 hours
children 6 to under 12 years of age	take 1/2 teaspoonful (2.5 mL) every 4 hours
children 2 years to under 6 years of age	ask a doctor
children under 2 years of age	do not use

Other Information

Store at room temperature 15°-30° (59°-86°).
Tamper evident feature: Do not use if cap seal is broken or missing.

Inactive ingredients Purified water, citric acid, methylparaben, glycerin, propylparaben, propylene glycol, sodium citrate, flavor, sucralose.

Questions or comments: 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, FL 33166.
www.advancedgeneric.com

**BIO T PRES-B**

brompheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-226
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	4 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (grape flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-226-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/01/2012	

Labeler - Advanced Generic Corporation (831762971)

Revised: 12/2012

Advanced Generic Corporation