

BIOTPRES- dextromethorphan, guaifenesin, phenylephrine 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
Dextromethorphan Hydrobromide 10 mg.....	Cough Suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg.....	Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passages of bothersome mucus
- temporarily relieves nasal congestion due to the common cold and cough due to minor throat and bronchial irritation.

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 you are taking a prescription drug that contains an MAOI; ask your doctor or pharmacist before taking this product.

Do not Use

- In a child under 2 years of age.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to the enlargement of the prostate gland
- a cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic as occurs with smoking, asthma, chronic bronchitis or emphysema

When using this product, do not exceed recommended dosage

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.

Keep out of reach of children.

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

Directions Do not exceed 6 doses in 24 hours.

adults and children 12 years of age and over take 2 teaspoonful (10 mL) every 4 hours

children 6 to under 12 years of age take 1 teaspoonful (5 mL) every 4 hours

children 2 to under 6 years of age take 1/2 teaspoonful (2.5 mL) every 4 hours

children under 2 years of age ask doctor

Other information store at room temperature 15° - 30°C (59° - 86°F).

Tamper evident by imprinted heat seal under cap. Do not use if there's evidence of tampering.

Warning:Phenylketonuric. Contains 17 mg of Phenylalanine per 5 mL (one teaspoonful dose).

Inactive Ingredients aspartame, citric acid, Cherry Flavor, FD and C Red No 40, glycerine, methylparaben,natrosol, propylene glycol, propylparaben, purified water, sodium citrate

Questions or comments? 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, Fl 33166

www.advancedgeneric.com

NDC 45737-225-16


BIOT PRES

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Sugar FREE • Sorbitol FREE
Alcohol FREE • Saccharin FREE

Contains the same active ingredients as Tussi-Pres[®]†

Cherry Flavor

Manufactured For: 
advanced generic corporation
Miami, Fl 33166
www.advancedgeneric.com


16 fl. oz. (473 mL)

Drug Facts	
Active ingredients (in each 5 mL tsp.)	
Dextromethorphan HBr, USP.....10 mg.....Cough Suppressant	Purpose
Guaifenesin, USP.....200 mg.....Expectorant	
Phenylephrine HCl, USP.....5 mg.....Nasal Decongestant	
Uses ■ helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes ■ temporarily relieves nasal congestion due to the common cold and cough due to minor throat and bronchial irritation	
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 you are taking a 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.	
Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to the enlargement of the prostate gland ■ a cough that occurs with too much phlegm (mucus) ■ cough that lasts or is chronic as occurs with smoking, asthma, chronic bronchitis or emphysema	
When using this product, do not exceed recommended dosage	
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.	
†Tussi-Pres [®] is a registered trademark of Kramer-Novis	

Drug Facts (continued)	
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 Do not exceed more than 6 doses in any 24-hour period.	
adults and children 12 years of age and over	take 2 teaspoonfuls (10 mL) every 4 hours
children 6 to under 12 years of age	take 1 teaspoonful (5 mL) every 4 hours
children 2 years to under 6 years of age	take 1/2 teaspoonful (2.5 mL) every 4 hours
children under 2 years of age	ask a doctor
Other information ■ store at room temperature 15° - 30°C (59° - 86°F). Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering.	
Warning: Phenylketonuric. Contains 17 mg of Phenylalanine per 5 mL (one teaspoonful) dose.	
Inactive ingredients aspartame, citric acid, cherry flavor, FD&C red #40, glycerin, methylparaben, natrosol, propylene glycol, propylparaben, purified water, sodium citrate.	
Questions or comments? 1-305-403-3788	
Manufactured For: Advanced Generic Corporation, Miami, Fl 33166. www.advancedgeneric.com	

Lot #: _____ Rev. 12/08

Exp. Date: _____



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BIOTPRES

dextromethorphan, guaifenesin, phenylephrine liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-225
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	15 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0K00R)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Aspartame (UNII: Z0H242BBR1)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
Hydroxymethyl Cellulose (UNII: 273FM27VK1)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (Cherry Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-225-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2009	

Labeler - Advanced Generic Corporation (831762971)