

BIONEL - dextromethorphan, guaifenesin, pseudoephedrine 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
Guaifenesin 200 mg	Expectorant
Dextromethorphan Hydrobromide 15 mg.....	Cough Suppressant
Pseudoephedrine HCl 30 mg.....	Nasal Decongestant

Uses

- temporarily relieves nasal congestion due to the common cold and thin bronchial secretions to make coughs more productive
- temporary relief of cough due to minor throat and bronchial irritation
- helps to control reflex that causes coughing

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 a MAOI; ask a doctor or pharmacist before taking this product.

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)
- a breathing problem or chronic cough that lasts or occurs with smoking, asthma, chronic bronchitis, or emphysema. A persistent cough may be a sign of a serious condition.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or 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 4 doses in 24 hours.

adults and children 12 years of age and over take 2 teaspoonful (10 mL) every 6 hours

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

children under 6 years of age ask a doctor

Other information

- store at controlled room temperature 20° - 25°C (68° - 77°F); excursion permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature]. Tamper evident by imprinted heat seal under cap. Do not use if there is evidence of tampering.

Warning: Phenylketonuric: Contains 19 mg of Phenylalanine per 5 mL (one teaspoonful) dose.

Inactive ingredients aspartame, citric acid, glycerine, methylparaben, natural and artificial flavors, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water

Questions or comments? 1-305-403-3788

Manufactured For: Advanced Generic Corporation, Miami, Fl 33166

www.advancedgeneric.com

Drug Facts

Active ingredients (in each 5 mL tsp.)	Purpose
Dextromethorphan HBr, USP.....15 mg	Cough Suppressant
Guaifenesin, USP.....200 mg	Expectorant
Pseudoephedrine HCl, USP.....30 mg	Nasal Decongestant

Uses • temporarily relieves nasal congestion due to the common cold and thin bronchial secretions to make coughs more productive
 • temporary relief of cough due to minor throat and bronchial irritation
 • helps to control reflex that causes coughing

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 a MAOI; ask a doctor or pharmacist before taking this product.

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) • a breathing problem or chronic cough that lasts or occurs with smoking, asthma, chronic bronchitis, or emphysema. A persistent cough may be a sign of a serious condition.

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 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. ➔

† **Tusnel® Liquid** is a registered trademark of Llorens Pharmaceutical

NDC 45737-206-16


BIONEL

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Sugar FREE • Dye FREE
Alcohol FREE • Saccharin FREE

Contains the same active ingredients as Tusnel® Liquid[†]

Manufactured For:



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

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 4 doses in any 24-hour period or as directed by a doctor.

Adults and children 12 years of age and over	take 2 teaspoonfuls (10 mL) every 6 hours
Children 6 to under 12 years of age	take 1 teaspoonful (5 mL) every 6 hours
Children under 6 years of age	ask a doctor

Other information • store at controlled room temperature 20° - 25°C (68° - 77°F); excursion permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature]. Tamper evident by Imprinted heat seal under cap. Do not use if there is evidence of tampering.
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Lot #: _____ Rev. 12/08

Exp. Date: _____

16 fl. oz. (473 mL)



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BIONEL

dextromethorphan, guaifenesin, pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-206
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

Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DD9F)	Pseudoephedrine Hydrochloride	30 mg in 5 mL
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Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
potassium citrate (UNII: EE90ONI6FF)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Propylene Glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Aspartame (UNII: Z0H242BBR1)	
methylparaben (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-206-16	473 mL in 1 BOTTLE		

Marketing Information

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

Labeler - Advanced Generic Corporation (831762971)

Revised: 1/2013

Advanced Generic Corporation