

BIONEL PEDIATRIC- 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 50 mg	Expectorant
Dextromethorphan Hydrobromide 5 mg.....	Cough Suppressant
Pseudoephedrine HCl 15 mg.....	Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily relieves these symptoms occurring with a cold: nasal congestion, cough due to minor throat and bronchial irritation.

Warnings

Do not use in a child who is 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 your child 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 more than 4 doses in any 24-hour period or as directed by a doctor.

Children 6 to under 12 years of age; 45 lbs to under 95 lbs; Take 2 teaspoonfuls (10mL) every 4 to 6 hours

Children 2 to under 6 years of age; 25 lbs to under 45 lbs; Take 1 teaspoonful (5mL) every 4 to 6 hours

Children under 2 years of age; Under 25 lbs; 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 14 mg of Phenylalanine per 5 mL (one teaspoonful) dose.

Inactive ingredients aspartame, citric acid, corn syrup, D and C Red No 33, methylparaben, natural and artificial flavors, potassium citrate, potassium sorbate, propylparaben, propylene glycol, 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.)

Dextromethorphan HBr, USP	5 mg	Cough Suppressant
Guaifenesin, USP	50 mg	Expectorant
Pseudoephedrine HCl, USP	15 mg	Nasal Decongestant

Uses • helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive • temporarily relieves these symptoms occurring with a cold: nasal congestion, cough due to minor throat and bronchial irritation.

Warnings • Do not use • in a child who is 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 child's prescription drug contains an MAOI; ask a doctor or pharmacist before giving this product.

Ask a doctor before use if your child have • heart disease • high blood pressure • thyroid disease • diabetes • a cough that occurs with too much phlegm (mucus) • a persistent or chronic cough such as occurs with asthma.

When using this product, do not exceed recommended dosage

Stop use and ask a doctor if • nervousness, dizziness or sleeplessness occurs • symptoms do not get better within 7 days or accompanied by fever • cough last more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. A persistent cough could be a sign of a serious condition. ➔

†Tusnel® Pediatric is a registered trademark of Llorens Pharmaceutical Corp.

NDC 45737-207-16

BIONEL

pediatric

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Alcohol FREE • Saccharin FREE

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

Manufactured For:



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

Drug Facts (continued)

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.

Age	Weight	Dose
Children 6 to under 12 years of age	45 lbs to under 95 lbs.	Take 2 teaspoonfuls (10 mL) every 4 to 6 hours
Children 2 to under 6 years of age	25 lbs to under 45 lbs.	Take 1 teaspoonful (5mL) every 4 to 6 hours
Children under 2 years of age	Under 25 lbs	Ask a doctor

Other information • store at controlled room temperature 20°- 25°C (68° - 77°F); excursions 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 #: _____

Exp. Date: _____

Rev. 12/08

16 fl. oz. (473 mL)



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BIONEL PEDIATRIC

dextromethorphan, guaifenesin, pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45737-207
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	5 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	50 mg in 5 mL
Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
corn syrup (UNII: 9G5L16BK6N)	
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)	
D&C Red No. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-207-16	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)

Revised: 12/2020

Advanced Generic Corporation