

BIONEL PEDIATRIC- dextromethorphan, guaifenesin, pseudoephedrine hydrochloride liquid
Advanced Generic Corporation

AGC-BionelPed 207

| 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 has

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- 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

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

16 fl. oz. (473 mL)

| 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.

| 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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Manufacture of For: Advanced Generic Corporation, Miami, FL 33166.
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Lot #: _____ Rev. 12/08

Exp. Date: _____



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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: 9D2RT19KYH) (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: 1VPU26JZ4) | |
| 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 Drug | M012 | 10/01/2009 | |

Labeler - Advanced Generic Corporation (831762971)