### 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.

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### **Drug Facts**

Active Ingredients : (in each 5 mL tsp.)PurposeGuaifenesin 50 mgExpectorant

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.

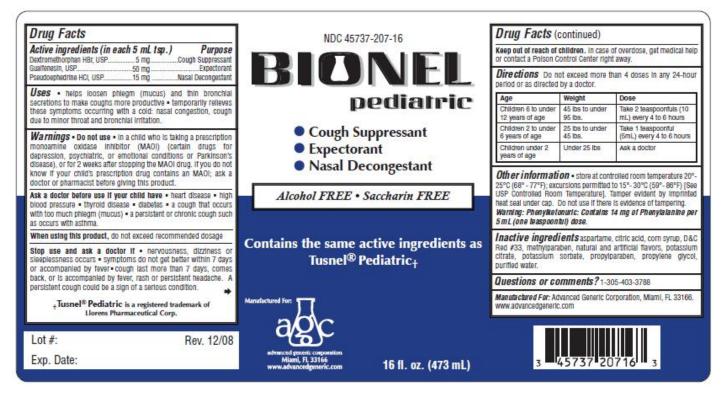
### Warning: Phenylketonuric: Contains 14 mg of Phenylalanine per 5 mL (one teaspoonful) dose.

**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



# **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 Moi	etv				
Ingredient Name			<b>Basis of Strength</b>		Strength
				ourengen	
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)		De xtro me tho rphan Hydro bro mide		5 mg in 5 mL	
Guaifenesin (UNII: 495W7451VQ) (Gua	ifenesin - UNII:495W7451VQ)		Guaifenesin		50 mg in 5 mL
Pseudoephedrine Hydrochloride (UN	II: 6 V9 V2RYJ8 N) (Pseudo ephedr	ine -	Pseudoephedrine		15 mg

Hydro chlo ride

in 5 mL

UNII:7CUC9DDI9F)

Inactive Ingredie	nte		
macuve mgreuie	Ingredient Name		Strength
corn syrup (UNII: 9G5	ottengti		
Water (UNII: 059QF0k	,		
potassium citrate (UN			
Potassium Sorbate (U			
Propylene Glycol (UN			
propylparaben (UNII:			
Citric Acid Monohyda	rate (UNII: 2968PHW8QP)		
Aspartame (UNII: Z0H			
methylparaben (UNII:	A2I8C7HI9T)		
D&C Red No. 33 (UNI	I: 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 Inf	ormation		
•		Maula da a Ctant Data	Maula da a Fad Data
Marketing Categor		Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/01/2009	

Labeler - Advanced Generic Corporation (831762971)

Revised: 12/2020

Advanced Generic Corporation