BIONEL - dextromethorphan, guaifenes in, 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

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.

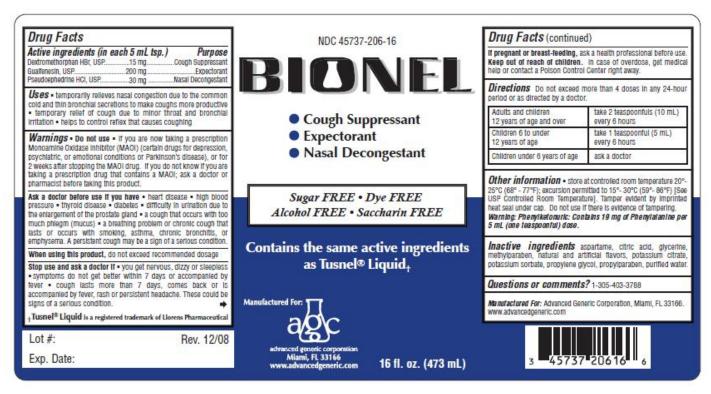
Warning: Phenylketonuric: Contains 19 mg of Phenylalanine per 5 mL (one teaspoonful) dose.

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



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)	Dextro metho rphan Hydro bro mide	15 mg in 5 mL	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg in 5 mL	

Pseudoephedrine Hydrochloride (UNII: 6 V9 V2RYJ8N) (Pseudoephedrine -	Pseudo e phe drine	30 mg
UNII:7CUC9 DDI9 F)	Hydro chlo ride	in 5 mL

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: 2968 PHW8 QP)		
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