BIO-S-PRES DX- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops
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 1mL) **Purpose**

Dextromethorphan HBr, 5 mg ..... Cough Suppressant

Guaifenesin, 50 mg ..... Expectorant

Phenylephrine HCl, 2.5 mg ..... Nasal Decongestant

Purpose

Cough Suppressant

Expectorant

Nasal Decongestant

Warnings:

Do not exceed recommended dosage.

- If nervousness, dizziness, or sleeplessness occurs, discontinue use and consult a doctor.
- If symptoms do not improve within 7 days or accompanied by fever, consult a doctor.

- **Do not use this product:**for persistent or chronic cough such as occurs with asthma, or if cough is accompanied by excessive phlegm (mucus), unless directed by a doctor.
- in a child who is taking a prescription Monoaminooxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for two 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.
- **Do not give** this product to child who has heart disease, high blood pressure, thyroid disease, or diabetes, unless directed by a doctor.
- **Stop use and ask a doctor:**
- A persistent cough may be a sign of a serious condition;
- If cough persists for more than one week, tend to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

Keep out of the reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions: Do not exceed more than 6 doses in any 24-hour period. Measure with the dosage device provided. Do not use with any other device.

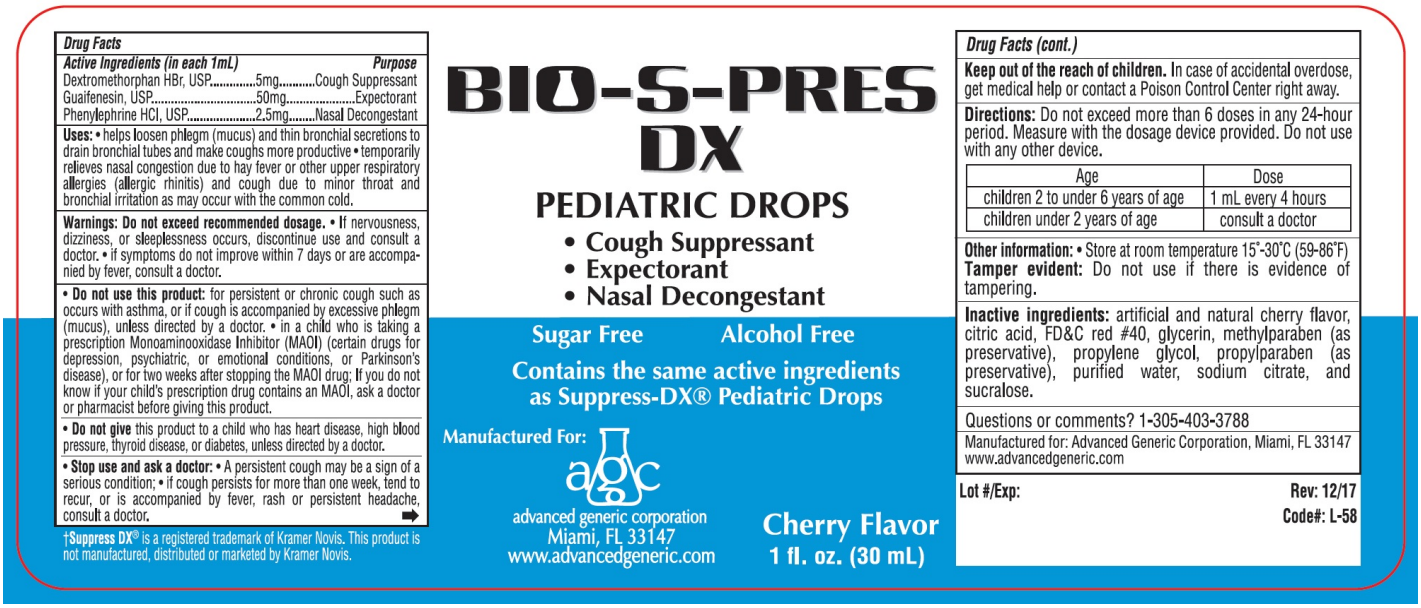
Age	Dose
Children 2 to under 6 years of age	1 mL every 4 hours
Children under 2 years of age	Consult a doctor

Inactive ingredients: Artificial and natural Cherry Flavor, Citric Acid, FD and C Red No. 40, Glycerin, Methyl Paraben (as preservative), Propylene Glycol, Propylparaben (as preservative), Purified Water, sodium citrate, and sucralose

Questions or comments? 1-305-403-3788

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
temporarily relieves nasal congestion due to hay fever or other upper respiratory allergies (allergic rhinitis) and cough due to minor throat and bronchial irritation as may occur with the common cold.



BIO-S-PRES DX

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:45737-230
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 1 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	50 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	CHERRY (Cherry Flavor)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-230-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2013	

Labeler - Advanced Generic Corporation (831762971)

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