

**BIO-S-PRES DX- dextromethorphan hbr, guaifenesin, phenylephrine
hcl solution/ drops
Advanced Generic Corporation**

AGC-BioSPressDX 230

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 Monoaminoxidase 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.

<p>Drug Facts</p> <p>Active Ingredients (in each 1mL)</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">Dextromethorphan HBr, USP.....5mg.....Cough Suppressant</td> <td style="width: 30%;">Purpose</td> </tr> <tr> <td>Guaifenesin, USP.....50mg.....Expectorant</td> <td></td> </tr> <tr> <td>Phenylephrine HCl, USP.....2.5mg.....Nasal Decongestant</td> <td></td> </tr> </table> <p>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.</p> <p>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 are accompanied by fever, consult a doctor.</p> <p>• 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 Monoamine oxidase 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.</p> <p>• Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes, unless directed by a doctor.</p> <p>• 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.</p> <p><small>†Suppress DX® is a registered trademark of Kramer Novis. This product is not manufactured, distributed or marketed by Kramer Novis.</small></p>	Dextromethorphan HBr, USP.....5mg.....Cough Suppressant	Purpose	Guaifenesin, USP.....50mg.....Expectorant		Phenylephrine HCl, USP.....2.5mg.....Nasal Decongestant		<h1 style="margin: 0;">BIO-S-PRES DX</h1> <h2 style="margin: 0;">PEDIATRIC DROPS</h2> <ul style="list-style-type: none"> Cough Suppressant Expectorant Nasal Decongestant <p style="margin: 0;">Sugar Free Alcohol Free</p> <p style="margin: 0;">Contains the same active ingredients as Suppress-DX® Pediatric Drops</p> <p style="margin: 0;">Manufactured For:</p> <p style="margin: 0; font-size: small;">advanced generic corporation Miami, FL 33147 www.advancedgeneric.com</p> <p style="margin: 0; font-size: small;">Cherry Flavor 1 fl. oz. (30 mL)</p>	<p>Drug Facts (cont.)</p> <p>Keep out of the reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.</p> <p>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.</p> <table border="1" style="width: 100%; border-collapse: collapse; font-size: x-small;"> <tr> <th style="width: 50%;">Age</th> <th style="width: 50%;">Dose</th> </tr> <tr> <td>children 2 to under 6 years of age</td> <td>1 mL every 4 hours</td> </tr> <tr> <td>children under 2 years of age</td> <td>consult a doctor</td> </tr> </table> <p>Other information: • Store at room temperature 15°-30°C (59-86°F) Tamper evident: Do not use if there is evidence of tampering.</p> <p>Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C red #40, glycerin, methylparaben (as preservative), propylene glycol, propylparaben (as preservative), purified water, sodium citrate, and sucralose.</p> <p style="font-size: x-small;">Questions or comments? 1-305-403-3788 Manufactured for: Advanced Generic Corporation, Miami, FL 33147 www.advancedgeneric.com</p> <p style="font-size: x-small;">Lot #/Exp: Rev: 12/17 Code#: L-58</p>	Age	Dose	children 2 to under 6 years of age	1 mL every 4 hours	children under 2 years of age	consult a doctor
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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: 405W7451VQ) (GUAIFENESIN - UNII:405W7451VQ)	GUAIFENESIN	50 mg

GUAIFENESIN (UNII: 493W7431VQ) (GUAIFENESIN - UNII:493W7431VQ)	GUAIFENESIN	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: 059QF0KOOR)	
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 Drug	M012	03/01/2013	

Labeler - Advanced Generic Corporation (831762971)