

**BIO-G-TUSS PEDIATRIC DROPS- dextromethorphan hbr, guaifenesin,  
phenylephrine hcl solution/ drops  
Advanced Generic Corporation**

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**AGC-BioGTuss Ped Dr 240**

**Active ingredients**

Dextromethorphan HBr

Guaifenesin

Phenylephrine HCl

**Purpose**

Cough Suppressant

Expectorant

Nasal Decongestant

**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 respiratory allergies (allergic rhinitis) and cough due to minor throat and bronchial irritation as may occur with the common cold

**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.

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.
- Do not give this product to a 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 onweek, tend to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

## Keep out of reach of children

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

## Directions

| Age                                 | Dose                 |
|-------------------------------------|----------------------|
| children 6 to under 12 years of age | 2 mL every 6-8 hours |
| children 2 to under 6 years of age  | 1 mL every 6-8 hours |
| children under 2 years of age       | consult a doctor     |

## Inactive ingredients

citric acid, grape flavor, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate, sucralose.

## Questions or Comments

1-305-403-3788

**Drug Facts**

| Active Ingredients (in each 1mL)     | Purpose            |
|--------------------------------------|--------------------|
| Dextromethorphan HBr..... 7.5mg..... | Cough Suppressant  |
| Guaifenesin..... 88mg.....           | Expectorant        |
| Phenylephrine HCl..... 2.5mg.....    | Nasal Decongestant |

**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.

**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.

• 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 Monoamineoxidase 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 a 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.

†Giltuss® Pediatric Drops is a registered trademark of Gil Pharmaceutical Corp. This product is not manufactured, distributed or marketed by Gil Pharmaceutical Corp.

NDC: 45737-240-02

# BIO-G-TUSS


## PEDIATRIC DROPS

- Cough Suppressant
- Expectorant
- Nasal Decongestant

Sugar Free    Dye Free    Alcohol Free

Contains the same active ingredients as Giltuss® Pediatric Drops†

Manufactured For:



advanced generic corporation  
Miami, FL 33166  
www.advancedgeneric.com

Grape Flavor  
2 fl. oz. (60 mL)

**Drug Facts (cont.)**

**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 recommended dose. Measure with the dosage device provided.

| Age                                 | Dose                 |
|-------------------------------------|----------------------|
| children 6 to under 12 years of age | 2 mL every 6-8 hours |
| children 2 to under 6 years of age  | 1 mL every 6-8 hours |
| children under 2 years of age       | consult a doctor     |

**Other information:** • Store at room temperature 15°-30°C (59-86°F)  
**Tamper evident:** Do not use if there is evidence of tampering.


**Inactive ingredients:** citric acid, grape flavor, glycerin, methylparaben, polyethylene glycol, propylparaben, purified water, sodium citrate, sucralose.

Questions or comments? 1-305-403-3788

Manufactured for: Advanced Generic Corporation, Miami, FL 33166  
www.advancedgeneric.com

Lot #/Exp: Rev: 04/14

NON-VARNISH



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## BIO-G-TUSS PEDIATRIC DROPS

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution/ drops

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:45737-240 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

| <b>Ingredient Name</b>  | <b>Basis of Strength</b>         | <b>Strength</b>   |
|---|----------------------------------|-------------------|
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH)<br>(DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN<br>HYDROBROMIDE | 7.5 mg<br>in 1 mL |
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                           | GUAIFENESIN                      | 88 mg<br>in 1 mL  |
| <b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)         | PHENYLEPHRINE                    | 2.5 mg<br>in 1 mL |

## Inactive Ingredients

| <b>Ingredient Name</b>                                     | <b>Strength</b> |
|--|-----------------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)            |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                         |                 |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)                    |                 |
| <b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A) |                 |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)                    |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                            |                 |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)                   |                 |
| <b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)                        |                 |

## Packaging

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                                    | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:45737-240-02 | 60 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 04/01/2016                  |                           |

## Marketing Information

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug        | M012  | 04/01/2016                  |                           |

**Labeler** - Advanced Generic Corporation (831762971)