

**GILTUSS CHILDRENS COUGH AND CHEST CONGESTION- dextromethorphan hydrobromide, guaifenesin solution**  
**Gil Pharmaceutical Corp**

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**Giltuss Children's Cough & Chest Congestion**

***Drug Facts***

***Active ingredients (in each 5 mL)***

Dextromethorphan HBr, 10 mg

Guaifenesin, 100 mg

***Purposes***

Cough Suppressant

Expectorant

***Uses***

- temporarily relieves
- cough due to minor throat and bronchial irritation associated with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help your child get to sleep
- helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive and drain bronchial tubes

***Warnings***

**Do not use** if your child is 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 your child's prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if the child has**

- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with asthma

**Stop use and ask a doctor or pharmacist if the child has**

- symptoms do not get better within 7 days or are accompanied by fever
- cough comes back, or is accompanied by fever, rash, or persistent headache.

These could be signs of a serious condition.

**When using this product**

- do not use more than directed.

**If pregnant or breast-feeding, ask a health professional before use.**

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

**Directions**

- do not take more than 6 doses in any 24 hour period
- use enclosed dosing cup
- keep dosing cup for use with this product
- mL = milliliters

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children under 2 years	Consult a doctor
children 2 to under 6 years of age	2.5 mL every 4 hours
children 6 to under 12 years of age	5 mL every 4 hours
children 12 years and over	10 mL every 4 hours

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**Other information**

- store at room temperature 15° - 30°C (59° - 86°F)
- close cap tightly
- **SAVE CARTON FOR COMPLETE DRUG FACTS**

**Inactive ingredients** Citric acid, flavor, D&C red #33, flavor, methylparaben, propylene glycol, propylparaben, purified water, and sucrose

**Questions or comments?**

Call **1-787-848-9114**, Monday - Friday 9AM - 5PM EST. Call your doctor for medical advice in the event of side effects.

**Tamper evident: do not use if safety seal is broken or missing**

**MANUFACTURED FOR**

**GIL PHARMACEUTICAL CORP.**

**PONCE, PUERTO RICO 00717-1565**

Children's

**GILTUSS®**

COUGH & CHEST CONGESTION

ANTITUSSIVE AND EXPECTORANT

Non-Drowsy. Alcohol Free

- COUGH AND COLD
- CHEST CONGESTION
- LIQUIFIES AND LOOSENS PHLEGM AND MUCUS

RASPBERRY FLAVOR

4FL OZ (118 mL)



## GILTUSS CHILDRENS COUGH AND CHEST CONGESTION

dextromethorphan hydrobromide, guaifenesin solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-133
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>SUCROSE</b> (UNII: C151H8M554)	

**ANHYDROUS CITRIC ACID** (UNII: XF417D3PSL)

**PROPYLPARABEN** (UNII: Z8IX2SC1OH)

**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)

**METHYLPARABEN** (UNII: A2I8C7HI9T)

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	RASPBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-133-04	1 in 1 CARTON	10/02/2018	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/02/2018	

**Labeler** - Gil Pharmaceutical Corp (176826592)

### Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58552-133)

Revised: 10/2025

Gil Pharmaceutical Corp