

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

-----  
**Childrens Giltuss Honey 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 coughs 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 persistent or chronic cough as occurs with asthma

**Stop use and ask a doctor if the child has** a cough lasts for 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.** 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 dosage cup for use with this product**
- ml = milliliters

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

**Other information**

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

**Inactive ingredients** carboxymethylcellulose sodium, citric acid, glycerin, natural and artificial flavor, natural grade A honey, methylparaben, propylene glycol, propylparaben, purified water, sucralose.

**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**

**[giltuss.com](http://giltuss.com)**

Children 4-12

**Children's Giltuss®**

Honey Cough & Chest Congestion

Made with real honey

Alcohol Free, Dye Free, Non Drowsy

COUGH AND COLD

CHEST CONGESTION

LIQUIFIES AND LOOSENS PHLEGM AND MUCUS

**HONEY LEMON FLAVOR**

**4FL OZ (118 mL)**



# CHILDRENS GILTUSS HONEY COUGH AND CHEST CONGESTION

dextromethorphan hbr, guaifenesin solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-141
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>HONEY</b> (UNII: Y9H1V576FH)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	

## Product Characteristics

<b>Color</b>	yellow (Light yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	HONEY, LEMON	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-141-04	1 in 1 CARTON	06/22/2020	
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	06/22/2020	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc		007392322	manufacture(58552-141)

