

**GILTUSS COUGH AND COLD- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution**  
**Gil Pharmaceutical Corp**

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**Giltuss Cough & Cold**

***Drug Facts***

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

Dextromethorphan HBr, 15 mg

Guaifenesin, 300 mg

Phenylephrine HCl, 10 mg

***Purposes***

Cough Suppressant

Expectorant

Nasal Decongestant

***Uses***

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive
- temporarily relieves nasal congestion due to a cold

***Warnings***

**Do not use** if you are 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- heart disease, high blood pressure, thyroid disease, or diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor
- a cough with too much phlegm (mucus)
- a persistent or chronic cough such as occurs with smoking, chronic bronchitis, or emphysema

**Ask a doctor or pharmacist before use if you are** taking any other oral nasal decongestant or stimulant, sedatives, tranquilizers, and drugs for depression, especially monoamine oxidase inhibitors (MAOIs).

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts for more than 7 days, comes back, or occurs with fever, rash or persistent headache

These can be signs of a serious condition.

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

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

**Directions**

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

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adults and children 12 years & over	5 mL every 4 hours
children 6 to under 12 years of age	2.5 mL every 4 hours
children 2 to 6 years of age	1.25 mL every 4 hours
children under 2 years of age	Consult a doctor

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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, glycerin, hydroxyethylcellulose, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sorbitol solution, and 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**

MAXIMUM STRENGTH

**GILTUSS®**

COUGH & COLD

ALCOHOL FREE. SUGAR FREE. DYE FREE

RELIEVES

- COUGH AND COLD
- CHEST CONGESTION
- LOOSENS PHLEGM AND MUCUS
- STUFFY NOSE
- NASAL CONGESTION

• SINUS PRESSURE

4 FL OZ (118 mL)



GILTUSS COUGH AND COLD			
dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-130
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL	

<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	300 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%)</b> (UNII: S38J6RZN16)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-130-04	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(58552-130)

