

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

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**Giltuss Children's Cough & Cold**

***Drug Facts***

**Active ingredients (in each 2.5 mL)**

Dextromethorphan HBr 7.5 mg

Guaifenesin 150 mg

Phenylephrine HCl 5 mg

**Purposes**

Cough Suppressant

Expectorant

Nasal decongestant

***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
- helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive and drain bronchial tubes
- stuffy nose

***Warnings***

**Do not use**

- to sedate a child or make a child sleepy
- 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 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 giving this product.

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with

asthma or chronic bronchitis

**Ask a doctor or pharmacist before use if the child is**

- taking any other oral nasal decongestant or stimulant
- taking sedatives, tranquilizers
- **Stop use and ask a doctor if**
- nervousness, dizziness, or sleepless occurs
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts 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 overdose, get medical help or contact a Poison Control Center right away.

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

Children's

**GILTUSS®**

**COUGH & COLD**

**ANTITUSSIVE, EXPECTORANT, NASAL DECONGESTANT**

Alcohol Free. Sugar Free. Dye Free.

- COUGH AND COLD
- CHEST CONGESTION
- STUFFY NOSE
- NASAL CONGESTION
- LOOSEN PHLEGM AND MUCUS
- SINUS PRESSURE

CHERRY FLAVOR

4 FL OZ (118 mL)

**Drug Facts**

Active ingredients (in each 2.5 mL)

Active ingredients (in each 2.5 mL)	Purposes
Dextromethorphan HBr 7.5 mg	Cough Suppressant
Guaifenesin 100 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- temporarily relieves
- cough due to minor throat and bronchial irritation associated with the common cold or irritated infants
- the intensity of coughing
- the impulse to cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive and drain bronchial tubes
- stuffy nose

**Warnings**

Do not use

- to sedate a child or to make a child sleepy
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or nutritional 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 giving this product.

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with asthma or chronic bronchitis

**Ask a doctor or pharmacist before use if the child is**

- taking any other oral nasal decongestant or stimulant
- taking sedatives or tranquilizers
- Stop use and ask a doctor if
- nervousness, dizziness, or sleepless occurs
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back or is accompanied by fever, rash, or persistent headache

These could 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 overdose, get medical help or contact a Poison Control Center right away.

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MANUFACTURED FOR  
GIL PHARMACEUTICAL CORP.  
PONCE, PUERTO RICO 00717-1565

**giltuss.com**

**Drug Facts (continued)**

**Directions**

- do not exceed recommended dosage
- 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 = milliliter

	Consult a Doctor
children under 2 years	1.25 mL every 4 hours
children 2 to under 6 years	2.5 mL every 4 hours
children 6 to under 12 years	2.5 mL every 4 hours
children 12 years and over	5 mL every 4 hours

**Other Information**

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

**Inactive ingredients**

citric acid, flavor, glycerin, hydroxyethyl cellulose, 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.

**Children's**  
**Niños 2-12**

**Giltuss**  
**COUGH & COLD**  
**TOS Y CATARRO**

Alcohol Free. Sugar Free. Dye Free.  
Sin Alcohol. Sin Azúcar. Sin Colorantes.

**COUGH & COLD**  
**TOS Y CATARRO**

**CHEST**  
**CONGESTION**  
**CONGESTION**  
**DE PECHO**

**STUFFY**  
**NOSE**  
**NARIZ TAPADA**

**NASAL**  
**CONGESTION**  
**CONGESTION**  
**NASAL**

**LOOSEN PHLEGM**  
**AND MUCUS**  
**SUELTA LA FLEMA**  
**Y EL MOCO**

**SINUS**  
**PRESSURE**  
**PRESIÓN NASAL**

**Non-Drowsy. No Causa Sueño.**

**Non-Drowsy. No Causa Sueño.**

CHERRY FLAVOR  
SABOR A CEREZA

4 FL OZ (118 mL)

**GILTUSS CHILDRENS COUGH AND COLD**

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-131
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 2.5 mL
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	150 mg in 2.5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 2.5 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:58552-131-04	1 in 1 CARTON	11/07/2018	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M012	11/07/2018	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58552-131)

Revised: 10/2023

Gil Pharmaceutical Corp