

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

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

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

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)

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.

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

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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

children under 2 years	Consult a Doctor
children 2 to under 6 years	1.25 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 (50°-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.

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING. NO LO USE SI LA TIRILLA EN LA TAPA ESTÁ ROTA O FALTA.

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ANTITUSSIVE, EXPECTORANT, & NASAL DECONGESTANT
ANTITUSSIVO, EXPECTORANTE & DESCONGESTIONANTE NASAL

Children Niños 2-12

G

Children's
Giltuss
COUGH & COLD
TOS Y CATARRO

Antitussive strength to control cough and cold symptoms
Fuerza antitusiva para controlar la tos y el catarro

Expectorant power to liquify and loosen phlegm and mucus
Poder expectorante para licuar y soltar la flema y el moco

Decongestant efficacy to relieve sinus pressure & nasal congestion
Eficacia descongestionante para el alivio de presión por sinusitis y congestión nasal

Non-Drowsy. No Causa Sueño.

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
SUELTAR LA FLEMA Y EL MOCO

SINUS PRESSURE
PRESION NASAL

CHERRY FLAVOR
SABOR A CEREZA

4 FL OZ (118 mL)

GILTUSS CHILDRENS COUGH AND COLD

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 2.5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	150 mg in 2.5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 2.5 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

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: 10/2025

Gil Pharmaceutical Corp