

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

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

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

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

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	300 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 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:58552-130-04	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)

