

GILTUSS CHILDRENS COUGH AND CHEST CONGESTION- dextromethorphan hydrobromide, guaifenesin solution
Gil Pharmaceutical Corp

Giltuss Children's 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 cough 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 breathing problem or persistent or chronic cough that lasts such as occurs with asthma

Stop use and ask a doctor or pharmacist if the child has

- symptoms do not get better within 7 days or are accompanied by fever
- cough comes back, or is accompanied by fever, rash, or persistent headache.

These could be signs of a serious condition.

When using this product

- do not use more than directed.

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 take more than 6 doses in any 24 hour period
- use enclosed dosing cup
- 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	2.5 mL every 4 hours
children 6 to under 12 years of age	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 Citric acid, flavor, D&C red #33, flavor, methylparaben, propylene glycol, propylparaben, purified water, and sucrose

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 & CHEST CONGESTION

ANTITUSSIVE AND EXPECTORANT

Non-Drowsy. Alcohol Free

- COUGH AND COLD
- CHEST CONGESTION
- LIQUIFIES AND LOOSENS PHLEGM AND MUCUS

RASPBERRY FLAVOR

4FL OZ (118 mL)



GILTUSS CHILDRENS COUGH AND CHEST CONGESTION

dextromethorphan hydrobromide, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-133
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
WATER (UNII: 059QF0KOOR)	
SUCROSE (UNII: C151H8M554)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

METHYLPARABEN (UNII: A2I8C7HI9T)

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-133-04	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(58552-133)

Revised: 10/2023

Gil Pharmaceutical Corp