CHILDRENS GILTUSS HONEY COUGH AND CHEST CONGESTIONdextromethorphan hbr, guaifenesin solution Gil Pharmaceutical Corp

Childrens Giltuss Honey 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 coughs more productive and drain bronchial tubes

Warnings

Do not useif 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 persistent or chronic cough as occurs with asthma

Stop use and ask a doctor if the child hasa cough lasts for more than 7 days, comes back, or is accompanied by fever, rash or persistent headache. These could be signs of a serious condition.

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 dosinc cup
- keep dosage cup for use with this product
- ml = milliliters

children under 4 years	Consult a doctor
children 4 to under 6 years	2.5 mL every 4 hours
children 6 to under 12 years	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 carboxymethycellulose sodium, citric acid, glycerin, natural and artificial flavor, natural grade A honey, methylparaben, propylene glycol, propylparaben, purified water, 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

giltuss.com

Children 4-12

Children's Giltuss®

Honey Cough & Chest Congestion

Made with real honey

Alcohol Free, Dye Free, Non Drowsy

COUGH AND COLD

CHEST CONGESTION

LIQUIFIES AND LOOSENS PHLEGM AND MUCUS

HONEY LEMON FLAVOR

4FL OZ (118 mL)



CHILDRENS GILTUSS HONEY COUGH AND CHEST CONGESTION

dextromethorphan hbr, quaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-141
Route of Administration	ORAL		

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

Inactive Ingredients				
Ingredient Name	Strength			
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K6790BS311)				
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
HONEY (UNII: Y9H1V576FH)				
METHYLPARABEN (UNII: A218C7H19T)				
PROPYLPARABEN (UNII: Z8IX2SC10H)				

Product Characteristics				
Color	yellow (Light yellow)	Score		
Shape		Size		
Flavor	HONEY, LEMON	Imprint Code		
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58552-141- 04	1 in 1 CARTON	06/22/2020		
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	06/22/2020		

Labeler - Gil Pharmaceutical Corp (176826592)

Establishment				
Name	Address	ID/FEI	Business Operations	
Dextrum Laboratories Inc		007392322	manufacture(58552-141)	

Revised: 10/2023 Gil Pharmaceutical Corp