

CHILDRENS GILTUSS HONEY DM COUGH- dextromethorphan hbr solution
Gil Pharmaceutical Corp

Giltuss Honey DM, Childrens

Drug Facts

Active ingredient (in each 5 mL)

Dextromethorphan HBr, 15 mg

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

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 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 such as occurs with asthma

Stop use and ask a doctor if the child has a cough that 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 4 doses in any 24-hour period
- **use enclosed dosing 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 6-8 hours
children 6 to under 12 years	5 mL every 6-8 hours
children 12 years and over	10 mL every 6-8 hours

Other information

- store at room temperature 15°-30°C (59°-86°F)
- close cap tightly

- **SAVE CARTON FOR COMPLETE DRUG FACTS**

Inactive ingredients natural and artificial flavor, natural grade A honey, methylparaben, potassium sorbate, 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 DM Cough

Alcohol Free. Dye Free. Non Drowsy.

PERSISTENT COUGH UP TO 8 HOURS

Made with real honey

HONEY LEMON FLAVOR.

4FL OZ (118 mL)

Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL	
Inactive Ingredients				
Ingredient Name		Strength		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
HONEY (UNII: Y9H1V576FH)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
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:58552-144-04	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(58552-144)