

GILTUSS HONEY COUGH AND CHEST CONGESTION- dextromethorphan hbr, guaifenesin liquid

Dextrum Laboratories, Inc

Giltuss Honey Cough & Chest Congestiion

Indication and user panel

Drug Facts

Active Ingredients
(in each 10 mL)
Dextromethorphan HBr, 20 mg
Guaifenesin, 200 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 you are 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have • a cough with too much phlegm (mucus) • a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if 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.

MAXIMUM STRENGTH. MÁXIMA CONCENTRACIÓN.
ALLERGEN FREE.
SWEET FLAVOR.
NO ARTIFICIAL SWEETENERS.
NO CHINA SULFON.

Giltuss Honey
Cough & Chest Congestion

TRUE SOURCE CERTIFIED HONEY

Directions • do not take more than 6 doses in any 24-hour period • use enclosed dosing cup
• keep dosage cup for use with this product
• mL = milliliters

adults and children 12 years and over	10 mL every 4 hours
children 6 to under 12 years of age	5 mL every 4 hours
children 4 to under 6 years of age	2.5 mL every 4 hours
children under 4 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
carboxymethylcellulose 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.

MANUFACTURED FOR
GIL PHARMACEUTICAL CORP.
PO BOX 10000, PUERTO RICO 00711-1565

giltuss.com

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100% FREE OF SUGAR, SWEETENED WITH ASPARTAME AND CALCIUM SUCRALFATE.

G

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Giltuss

Honey

Cough & Chest Congestion

TOSS Y CONGESTIÓN DE PECHO

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

TOS Y CATARRO, CONGESTIÓN DE PECHO, LÍQUIDA Y SUELTA LA FLEMA Y EL MOCO

HONEY FLAVOR SAVOR SAVOR A MIEL Y LIMÓN. 4 FL OZ (118 mL)

Drug Facts (continued).

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.

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PO BOX 10000 PUERTO RICO 00717-1565

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Purposes:

Sough suppressant

Expectorant

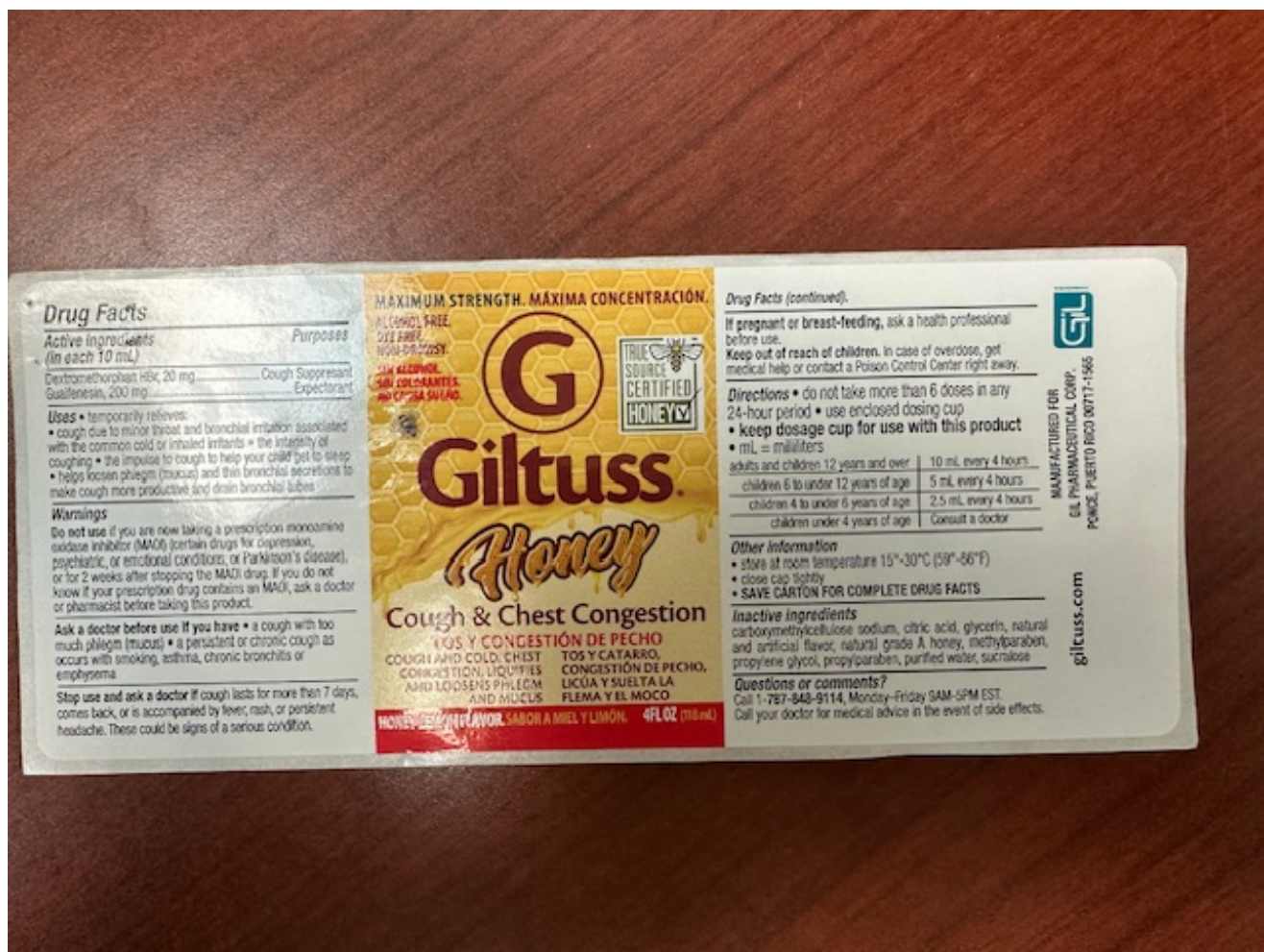
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Pregnant or breast feedings

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ALCOHOL FREE.
SIN ALCOHOL.
SIN COLORANTES
Y SIN AZÚCAR.

G

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CERTIFIED
HONEY

Giltuss

Honey

Cough & Chest Congestion

TOSS Y CONGESTIÓN DE PECHO
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G

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Cough & Chest Congestion

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COUGH AND COLD, CHEST
CONGESTION, LIQUIFIES
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GIL PHARMACEUTICAL CORP.
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gil

giluss.com

principal display panel



Maximum strength. Maxima Concentracion

Alcohol Free

Dye free

Non-Drowsy

True source

Certified Honey

Giltuss Honey Cough % Chest Congestion

Tos y congestion de Pecho

cough and cold, chest Tos y catarro,

Congestion, liquifies Congestion de Pecho,

and loosens phlegm and mucus Licua y suelt LA FLEMA Y EL MOCO

Honey Lemon flavor. Sabor a Miel y limon 4FL OZ (118ml)

GILTUSS HONEY COUGH AND CHEST CONGESTION

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65852-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
GLYCERIN (UNII: PDC6A3C0OX)	
HONEY (UNII: Y9H1V576FH)	
CITRIC ACID (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65852-005-04	1 in 1 CARTON	06/22/2020	
1		118 mL in 1 BOTTLE, PLASTIC; 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 - Dextrum Laboratories, Inc (007392322)