

CHILDRENS GILTUSS HONEY COUGH AND CHEST CONGESTION-
dextromethorphan hbr, guaifenesin solution
Dextrum Laboratories, Inc

Children's Giltuss Honey Cough & Chest Congestion

Active Ingredients

Active Ingredients (in Each 5 ml) Purposes

Dextromethorphan HBr, 10 mg -----Cough Suppressant

Guaifenesin, 100 mg -----Expectorant

Drug Facts

<i>Active ingredients (in each 5 mL)</i>	<i>Purposes</i>
Dextromethorphan HBr, 10 mg	Cough Suppressant
Guaifenesin, 100 mg	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

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 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.

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Temporary 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

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Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, get medical or professional help or contact a Poison Control center immediately

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Do not take more than 6 doses in any 24 hours period

use enclosed dosing cup

Keep dosage cup for use with this product

ml= milliliters

children under 4 years of age Consult a doctor

children 4 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

Adults and children 12 years & over 10 ml every 4 hours

Drug Facts (continued).

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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.
PONCE, PUERTO RICO 00717-1565

For most recent product information,
visit www.giltuss.com

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Children Niños 4-12
ALCOHOL FREE
DYE FREE
NON-BROWSTY.
SIN ALCOHOL
SIN COLORANTES
NO CHISA SUEÑO.
Made with Real Honey
For the right kind of Honey

G **Children's Giltuss Honey**
COUGH & CHEST CONGESTION
TOS Y CONGESTIÓN DE PECHO
COUGH & COLD, CHEST
CONGESTION, LIQUIDS AND
LOOSEN PHLEGM AND MUCUS
TOS Y CATARRO, CONGESTION
DE PECHO, LÍQUIDA Y
SUELTA LA FLEMA Y EL MOCO
HONEY LEMON FLAVOR.
SABOR A MIEL Y LIMÓN.
4FL OZ (118 mL)

Drug Facts (continued).

Directions

- do not take more than 6 doses in any 24-hour period
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- SAVE CARTON FOR COMPLETE DRUG FACTS

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Children
Niños
4-12

ALCOHOL FREE.
DYE FREE.
NON-DROWSY.

SIN ALCOHOL.
SIN COLORANTES.
NO CAUSA SUEÑO.

Made with Real Honey
Hecho con Miel Real



Children's
Giltuss.
Honey

**COUGH & CHEST CONGESTION
TOS Y CONGESTIÓN DE PECHO**

COUGH & COLD, CHEST
CONGESTION, LIQUIFIES AND
LOOSEN PHLEGM AND MUCUS
TOS Y CATARRO, CONGESTIÓN
DE PECHO, LICÚA Y
SUELTA LA FLEMA Y EL MOCO

HONEY LEMON FLAVOR.
SABOR A MIEL Y LIMÓN.

4FL OZ (118 mL)

Alcohol free, Dye free, Non-drowsy

True source certified honey

Children's Giltuss Honey

Cough & Chest Congestion

Cough & cold, chest congestion, liquifies and loosen phlegm and mucus

Honey lemon flavor

4 floz 118 ml

CHILDRENS GILTUSS HONEY COUGH AND CHEST CONGESTION

dextromethorphan hbr, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65852-003
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
CITRIC ACID (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
HONEY (UNII: Y9H1V576FH)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	HONEY (Lemon)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65852-003-04	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)