

GILTUSS CHILDRENS COUGH AND COLD- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution
Dextrum Laboratories Inc.

Children's Giltuss Cough & Cold

Drug Facts

Drug Facts

<i>Active ingredients (in each 2.5 mL)</i>	<i>Purposes</i>
Dextromethorphan HBr, 7.5 mg.....	Cough Suppressant
Guaifenesin, 150 mg	Expectorant
Phenylephrine HCl, 5 mg.....	Nasal Decongestant

Uses • temporarily relieves: • cough due to minor throat and bronchial irritation as may occur 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 • temporarily relieves nasal congestion due to a cold • stuffy nose

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 your child has • heart disease, high blood pressure, thyroid disease, diabetes, • a cough with too much phlegm (mucus) • a persistent or chronic cough as

occurs with asthma or chronic bronchitis

Ask a doctor or pharmacist before use if your child is taking any other oral nasal decongestant or stimulant, sedatives, tranquilizers, and drugs used for depression, especially monoamine oxidase inhibitors (MAOIs) • When

Active Ingredients (in each 2.5 ml) Purposes

Dextrometorphan HBr, 7.5 mg -----Cough suppressant

Guaifenesin, 150 mg -----Expectorant

Phenylephrine HCL, 5 mg -----Nasal Decongestant

Use section

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Stop use and ask a Doctor if * nervousness, dizziness or sleeplessness occur* symptom do not get better within 7 days or are accompanied by fever* cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache . These could be signs of serious conditions.

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If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of accidental overdose, get medical or professional help or contact a Poison Control Center immediately.

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

children under 4 years	Consult a Doctor
children 4 to under 6 years	1.25 mL every 4 hours
children 6 to under 12 years	2.5 mL every 4 hours
children 12 years and over	5 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, glycerin, hydroxyethyl cellulose, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sorbitol solution and 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.



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GIL PHARMACEUTICAL CORP.
PONCE, PUERTO RICO 00717-1565

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

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Active ingredients section

Active ingredients (in each 2.5 ml)

Dextrometorphan HBr, 7.5 mg

Guaifenesin, 150 mg

Drug Facts

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Purposes

Dextromethorphan HBr, 7.5 mg..... Cough Suppressant

Guaifenesin, 150 mg Expectorant

Phenylephrine HCl, 5 mg..... Nasal Decongestant

Uses • temporarily relieves: • cough due to minor throat and bronchial irritation as may occur 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 • temporarily relieves nasal congestion due to a cold • stuffy nose

Warnings

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Ask a doctor before use if your child has • heart disease, high blood pressure, thyroid disease, diabetes, • a cough with too much phlegm (mucus) • a persistent or chronic cough as occurs with asthma or chronic bronchitis

Ask a doctor or pharmacist before use if your child is taking any other oral nasal decongestant or stimulant, sedatives, tranquilizers, and drugs used for depression, especially monoamine oxidase inhibitors (MAOIs) • When



Inactive Ingredients

Inactive Ingredients

Citric Acid, Flavor, Glycerin, Hydroxyethylcellulose, methylparaben, polyethylene glycol, propylene glycol, propylparaben, purified water, sorbitol solution, and sucralose

Keep out of reach of children

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In case of accidental overdose , get medical or professional help or contact a Poison Control Center immediatly

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Active ingredients (in each 2.5 mL):
 Dextromethorphan HBr, 7.5 mg. Cough Suppressant
 Guaifenesin, 150 mg. Expectorant
 Phenylephrine HCl, 5 mg. Nasal Decongestant

Uses • Temporarily relieves • cough due to many throat and bronchial irritations it may occur with the common cold or flu and returns • 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 then breathe easier • temporarily relieves nasal congestion due to a cold • stuffy nose

Warnings
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 Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • symptoms do not get better within 7 days or are accompanied by fever • cough lasts for more than 7 days comes back, or is accompanied by fever, rash, or persistent headache. There could be signs of a serious condition.
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 Directions • not take more than 6 doses in any 24-hour period • use enclosed dosing cup • keep dosing cup for use with this product • mL = milliliter

Children under 4 years	Consult a Doctor
Children 4 to under 6 years	1.25 mL every 4 hours
Children 6 to under 12 years	2.5 mL every 4 hours
Children 12 years and over	5 mL every 4 hours

Other information • store at room temperature 15°-30°C (59°-86°F) • close cap tightly • **SAFE CARTON FOR COMPLETE DRUG FACTS**
 Inactive ingredients: citric acid, flavor, glycerin, hydroxyethyl cellulose, methylcellulose, polyethylene glycol, preservative, polysorbate, purified water, sorbic acid, and sucrose.

Questions or comments? Call 1-787-948-9114, Monday-Friday 9AM-5PM EST. Call your doctor for medical advice in the event of side effects.

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Indication and Usage section

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no take more than 6 doses in any 24 hours period

use enclosed dosing cup* keep dosage cup for use with this product* ml= milliliter

Children under 4 years ----Consult a doctor

children 4 to under 6 years-----1.25 ml every 4 hours

children 6 to under 12 years-----2.5 ml every 4 hours

children 12 yeras and over -----5 ml every 4 hours

Drug Facts

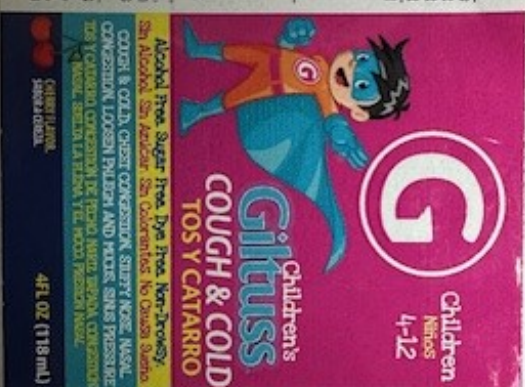
Active ingredients (in each 2.5 mL):
 Dextromethorphan HBr, 7.5 mg Cough Suppressant
 Guaifenesin, 150 mg Expectorant
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 If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of accidental overdose, get medical or poison control help or contact a Poison Control Center immediately.
 Directions • not take more than 6 doses in any 24-hour period • use endosed dosing cap • keep dosing cap for use with this product • mL = milliliter

Children under 4 years	Consult a Doctor
Children 4 to under 6 years	1.25 mL every 4 hours
Children 6 to under 12 years	2.5 mL every 4 hours
Children 12 years and over	5 mL every 4 hours

Other information • store at room temperature 15°-30°C (59°-86°F) • close cap tightly • **SAFE, CAUTION FOR COMPLETE DRUG FACTS**
 Inactive ingredients: citric acid, flavor, glycerin, hydroxyethyl cellulose, methylcellulose, polyethylene glycol, propylene glycol, polysorbate, purified water, sorbitol solution and sucrose.

Questions or comments? Call 1-787-948-9114, Monday-Friday 9AM-5PM EST. Call your doctor for medical advice in the event of side effects.

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Purpose section

Purpose section

Cough Suppressant

Expectorant

Nasal decongestant

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Active ingredients (in each 2.5 mL)	Purposes
Dextromethorphan HBr, 7.5 mg	Cough Suppressant

Guafenesin, 150 mg	Expectorant
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..... Natural background

- **surgically relieve:** cough due to narrow throat and bronchial irritation is may occur with the common cold or treated asthma
- **the intensity of coughing:** the impulse to cough to help your chest get to sleep
- **helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive and drain bronchus tubes**
- **surgically relieve nasal congestion due to a cold**
- **cold, stuffy nose**

Warning

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Ask a doctor before use if your child has: heart disease, high blood pressure, thyroid disease, diabetes, • a cough with too much phlegm (mucus) • a persistent or chronic cough as occurs with asthma or chronic bronchitis

Ask a doctor or pharmacist before use if your child is taking any other oral nasal otopreparatory or stimulant, sedatives, tranquilizers, and drugs used for depression, especially monoamine oxidase inhibitors (MAOIs). • When

[illegible]

using this product do not use more than directed

Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • symptoms do not get better within 7 days or are accompanied by fever • cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. Do not use for more than 10 days unless directed by a doctor.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of accidental ingestion, get medical or professional help or contact a Poison Control Center immediately.

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

children under 4 years	Consult a Doctor
------------------------	------------------

children 4 to under 6 years	1 to 2 mL every 4 hours
children 6 to under 12 years	2.5 mL every 4 hours

children 12 years and over | 5 mL every 4 hours

Useful information • Store at room temperature 15-20°C (59°-68°F) • Close cap tightly • **SAVE CARTON FOR**

COMPLETE DRUG FACTS
Inactive ingredients: citric acid, flavor, glycerin, hydroxyethyl

cellulose, methylcellulose, polyethylene glycol, polyurethane glycol, polyvinylalcohol, purified water, sorbitol solution and sucrose

Questions or comments?
Call 1-781-848-9114. Monday-Friday 9AM-5PM EST.


Call your doctor for medical advice in the event of side effects.

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PONCE, PUERTO RICO 00717-1565



Childrens 4-12
Cough & Cold
Alcohol free
Sugar free
Dye free
Non -Drowsy
Cherry Flavor



Children
Niños
4-12



Children's
Giltuss.
COUGH & COLD
TOS Y CATARRO

Alcohol Free. Sugar Free. Dye Free. Non-Drowsy.
Sin Alcohol. Sin Azúcar. Sin Colorantes. No Causa Sueño.

COUGH & COLD, CHEST CONGESTION, STUFFY NOSE, NASAL
CONGESTION, LOOSEN PHLEGM AND MUCUS, SINUS PRESSURE
TOS Y CATARRO, CONGESTION DE PECHO, NARIZ TAPADA, CONGESTION
NASAL, SUELTA LA FLEMA Y EL MOCO, PRESION NASAL.



CHERRY FLAVOR.
SABOR A CEREZA.

4FL OZ (118mL)

GILTUSS CHILDRENS COUGH AND COLD

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65852-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 2.5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 2.5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	150 mg in 2.5 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
CITRIC ACID (UNII: 2968PHW8QP)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65852-011-04	1 in 1 CARTON	11/07/2018	
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	11/07/2018	

Labeler - Dextrum Laboratories Inc. (007392322)

Revised: 9/2025

Dextrum Laboratories Inc.