

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

Giltuss Cough and Cold

Drug Facts

Active ingredients (in each 5 mL)

Purposes

Dextromethorphan HBr, 15 mg	Cough Suppressant
Guaifenesin, 300 mg	Expectorant
Phenylephrine HCl, 10 mg	Nasal Decongestant

Uses • temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants • helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive • temporarily relieves nasal congestion due to a cold

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 • heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate unless directed by a doctor • a cough with too much phlegm (mucus) • a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking any other oral nasal decongestant or stimulant, sedatives, tranquilizers, and drugs used for depression, especially monoamine oxidase inhibitors (MAOIs).

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Purpose Section & Uses

Cough suppressant

Expectorant

Nasal Decongestant

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Stop use

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
These can be signs of a serious condition.

If pregnant or breastfeeding, 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 • do not exceed recommended dosage • do not take more than 6 doses in any 24 hour period • keep dosing cup for use with this product • mL=milliliters

adults and children 12 years & over	5 mL every 4 hours
children 6 to under 12 years of age	2.5 mL every 4 hours
children 4 to 6 years of age	1.25 mL every 4 hours
children under 4 years of age	Consult a doctor

Other information

- store at room temperature, between 15°-30°C (59°- 86°F)
- keep tightly closed
- **SAVE CARTON FOR COMPLETE DRUG FACTS**

Inactive ingredients: Citric acid, flavor, glycerin, hydroxyethylcellulose, 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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PONCE, PUERTO RICO 00717-1565

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Pregnancy or breast feeding

Pregnancy 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.

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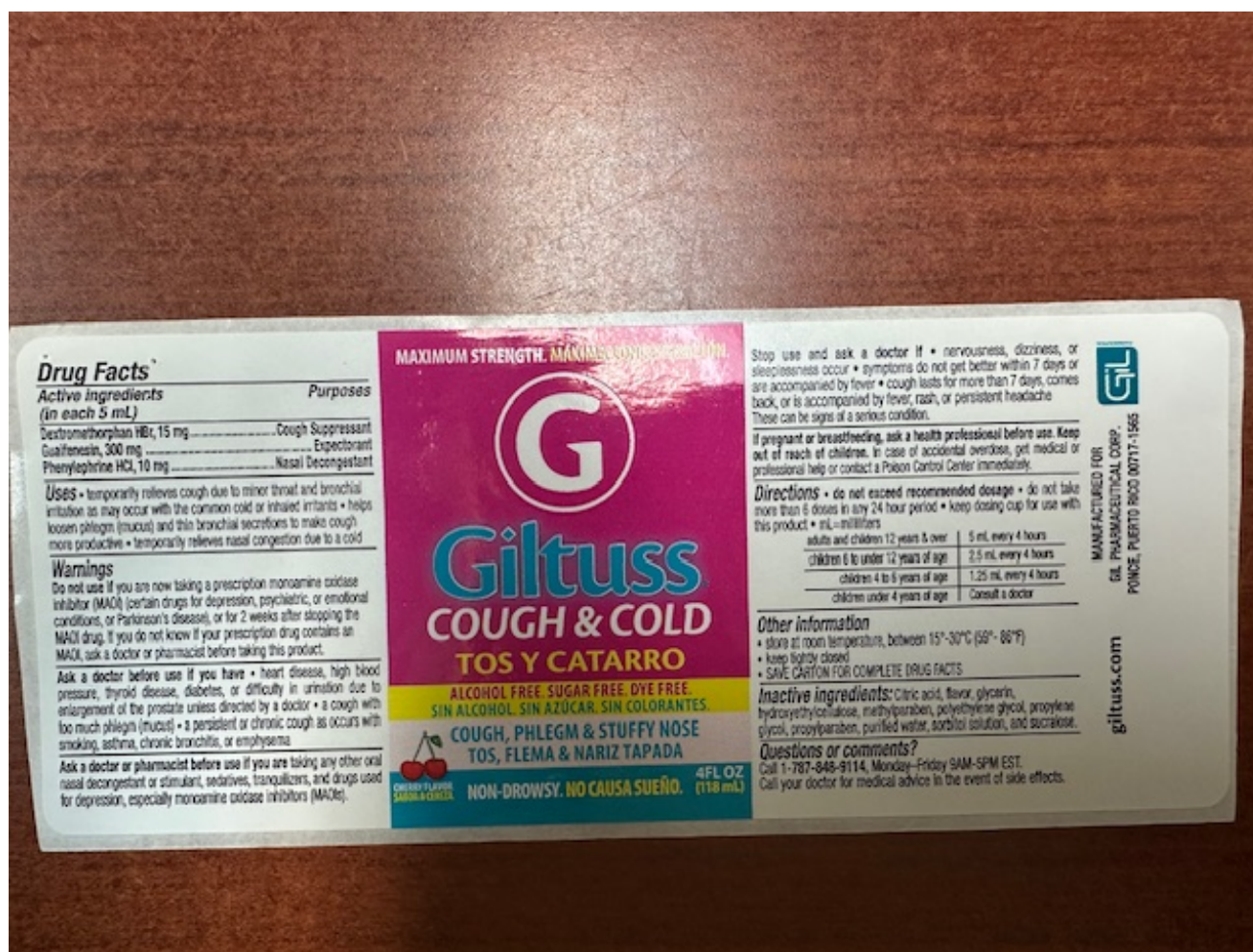
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Keep out of reach of children



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Indication and usage section

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Principal panel

maximun strength

Giltuss Cold & cold

Alcohol free

Sugar free

Dye free

Cough, Phlem & Stuffy nose

Non-drowsy

Cherry flavor

4 flox 118 ml

MAXIMUM STRENGTH. MÁXIMA CONCENTRACIÓN.



Giltuss
COUGH & COLD
TOS Y CATARRO

ALCOHOL FREE. SUGAR FREE. DYE FREE.
SIN ALCOHOL. SIN AZÚCAR. SIN COLORANTES.

COUGH, PHLEGM & STUFFY NOSE
TOS, FLEMA & NARIZ TAPADA



CHERRY FLAVOR
SABOR A CEREZA

NON-DROWSY. NO CAUSA SUEÑO.

4FL OZ
(118 mL)

GILTUSS COUGH AND COLD

dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65852-012
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	300 mg in 5 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65852-012-04	1 in 1 CARTON	10/02/2018	
1		113 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	10/02/2018	

Labeler - Dextrum Laboratories Inc. (007392322)

Revised: 9/2025

Dextrum Laboratories Inc.