

**GILTUSS CHILDRENS ALLERGY PLUS COUGH AND CONGESTION-
chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine
hydrochloride solution
Gil Pharmaceutical Corp**

Giltuss Children's Allergy Plus Cough & Congestion

Drug Facts

Active ingredients (in each 5 mL)

Chlorpheniramine maleate USP, 2 mg

Dextromethorphan HBr USP, 10 mg

Phenylephrine HCl USP, 5 mg

Purposes

Antihistamine

Cough Suppressant

Nasal decongestant

Uses

- temporarily relieves
- cough due to minor throat and bronchial irritation associated with a cold or inhaled irritants
- nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis):
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- temporarily restores freer breathing through the nose

Warnings

Do not use

- to sedate a child or to make a child sleepy
- in a child who is 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 the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes

- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with asthma

Ask a doctor or pharmacist before use if the child is

- taking sedatives or tranquilizers
- taking any other oral nasal decongestant or stimulant

When using this product

- **do not use more than directed**
- may cause marked drowsiness
- excitability may occur, especially in children

Stop use and ask a doctor if

- nervousness, dizziness, or sleepless occurs
- symptoms do not get better within 7 days or are accompanied by a fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash or persistent headache.

These could 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 overdose, get medical help or contact a Poison Control Center right away.

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=milliter**

children under 6 years	Consult a Doctor
children 6 to under 12 years	5 mL every 4 to 6 hours
adults and children 12 years and over	10 mL every 4 to 6 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, methylparaben, propylparaben, purified water 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.

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's

Giltuss® ALLERGY PLUS COUGH & CONGESTION

ANTIHISTAMINIC, ANTITUSSIVE, & NASAL DECONGESTANT

Alcohol Free. Sodium Free. Sugar Free. Dye Free.

- SNEEZING
- RUNNY NOSE
- COUGH
- ITCHY & WATERY EYES
- STUFFY NOSE
- SINUS PRESSURE

TUTTI FRUTTI FLAVOR

4 FL OZ (118 mL)

Drug Facts

Active ingredients (in each 5 mL):

Chlorpheniramine maleate, USP 2 mg Antihistamine
Dextromethorphan HBr, USP 10 mg Cough Suppressant
Phenylephrine HCl, USP 5 mg Nasal decongestant

(Uses)

- temporarily relieves
 - cough due to minor throat and bronchial irritation associated with a cold or irritated sinuses
 - nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis):
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of the nose or throat
- temporarily relieves fever resulting through the nose

Warnings
Do not use

- to sedate a child or to make a child sleep
- in a child who is 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 the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with asthma

Ask a doctor or pharmacist before use if the child is

- taking sedatives or tranquilizers
- taking any other oral nasal decongestant or stimulant.

When using this product

- do not use more than directed
- may cause marked drowsiness
- excitability may occur, especially in children

Stop use and ask a doctor if

- restlessness, dizziness, or sleepiness occurs
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache

These could be signs of a serious condition.

MANUFACTURED FOR
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PONCE, PUERTO RICO 00717-1565

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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.

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 6 years	Consult a Doctor
children 6 to under 12 years	3 mL, every 4 to 6 hours
adults and children 12 years and over	10 mL, every 4 to 6 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, methylparaben, propylparaben, purified water and sucralose

Questions or comments?
Call 1-787-848-0114 Monday-Friday 9AM-5PM EST.
Call your doctor for medical advice in the event of side effects.

Temper evidente, do not use if safety seal is broken or missing

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING.
NO LO USE SI LA TIRILLA EN LA TAPA ESTÁ ROTA O FALTA.

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ANTHISTAMINE, ANTITUSSIVE & NASAL DECONGESTANT
ANTIHISTAMÍNICO, ANTITUSSIVO Y DESCONGESTIONANTE NASAL

Children 6-12
Niños 6-12

G

Children's
Giltuss
ALLERGY PLUS
COUGH & CONGESTION
ALERGIA, TOS Y CONGESTIÓN

Fast antihistaminic efficacy to relieve sneezing, runny nose, and itchy and watery eyes from allergies.
Rápida eficacia antihistamínica para aliviar los estornudos, goteo nasal y el picor y ojos llorosos por las alergias.

Antitussive strength to control cough symptoms.
Fuerza antitusiva para controlar la tos.

Decongestant efficacy to relieve sinus pressure and nasal congestion.
Eficacia descongestionante para el alivio de presión por sinusitis y congestión nasal.

Alcohol Free. Sodium Free. Sugar Free. Dye Free.
Sin Alcohol. Sin Sodio. Sin Azúcar. Sin Colorantes.

SNEEZING
ESTORNUDOS

RUNNY NOSE
GOTEO NASAL

COUGH
TOS

ITCHY & WATERY EYES
PICOR Y OJOS LLOROSOS

STUFFY NOSE
NARIZ TAPADA

SINUS PRESSURE
PRESIÓN POR SINUSITIS

TASTE FREE FLAVOR
SABOR A NUTRIPURE

4 FL OZ (118 mL)

GILTUSS CHILDRENS ALLERGY PLUS COUGH AND CONGESTION

chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-139
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg	in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	in 5 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC10H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	yellow (Light yellow)	Score	
Shape		Size	
Flavor	TUTTI FRUTTI	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-139-04	1 in 1 CARTON	11/07/2018	
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	11/07/2018	

Labeler - Gil Pharmaceutical Corp (176826592)

Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58552-139)

Revised: 10/2023

Gil Pharmaceutical Corp