

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

Giltuss Allergy Plus Cough & Congestion

Drug Facts

Active ingredients (in each 10 mL)

Chlorpheniramine maleate, USP 4 mg

Dextromethorphan HBr, USP 20 mg

Phenylephrine HCl, USP 10 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
- 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
- trouble urinating due to enlargement of the prostate gland

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

Ask a doctor or pharmacist before use if you are

- 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
- avoid alcoholic beverages
- alcohol, sedatives and tranquilizers may increase drowsiness effect
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- 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, seek professional help or contact a Poison Control Center right away.

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=milliter**

adults and children 12 years and over	10 mL every 4 to 6 hours
children 6 to under 12 years	5 mL every 4 to 6 hours
children under 6 years	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

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

MAXIMUM STRENGTH

Giltuss® ALLERGY PLUS COUGH & CONGESTION

ANTIHISTAMINIC, ANTITUSSIVE, & NASAL DECONGESTANT

ALCOHOL FREE. SODIUM FREE. SUGAR FREE. DYE FREE.

RELIEVES

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

TUTTI FRUTTI FLAVOR

4FL OZ (118 mL)



GILTUSS ALLERGY PLUS COUGH AND CONGESTION

chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-138
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 04JA59TNSJ)	PHENYLEPHRINE	10 mg

UNII:1WS297W6MV)

HYDROCHLORIDE

in 10 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
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:58552-138-04	1 in 1 CARTON	10/02/2018	
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	10/02/2018	

Labeler - Gil Pharmaceutical Corp (176826592)**Establishment**

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc.		007392322	manufacture(58552-138)

Revised: 10/2023

Gil Pharmaceutical Corp