

GILTUSS ALLERGY PLUS- chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution
Dextrum Laboratories Inc.

Giltuss Allergy Plus Cough & Congestion

Active ingredients

Active ingredients (in each 10 m) Purposes

Chlorpheniramine maleate, USP 4 mg -----Antihistamine

Dextromethorphan HBr, USP 20 mg -----Cough supressant

Phenylephrine HCl, USP 10 mg -----Nasal descongellant

MAXIMUM STRENGTH. MÁXIMA CONCENTRACIÓN.



Giltuss.
ALLERGY PLUS
COUGH & CONGESTION
ALERGIA, TOS Y CONGESTIÓN

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

**SNEEZING, RUNNY NOSE, ITCHY AND WATERY EYES,
COUGH, STUFFY NOSE, SINUS PRESSURE**

**ESTORNUDOS, GOTEÓ NASAL, PICOR Y OJOS LLOROSOS,
TOS, NARIZ TAPADA, PRESIÓN POR SINUSITIS**



TUTTI FRUTTI FLAVOR.
SABOR A TUTTI FRUTTI.

4FL OZ (118 mL)

Uses

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Temporary relieves:

Cough due to minor throat and bronchial irritation associated with the common cold or inhaled irritants,

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4FL OZ (118 mL)

helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive, temporary relieves nasal congestion due to a cold

Warnings

Drug Facts

Active ingredients (in each 10 mL)	Purposes
Chlorpheniramine maleate, USP 4 mg	Antihistamine
Dextromethorphan HBr, USP 20 mg	Cough suppressant
Phenylephrine HCl, USP 10 mg	Nasal decongestant

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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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Ask a doctor

Ask a doctor before use if you have:

heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to an enlarged prostate unless directed by a doctor, a cough with too much phlegm (mucus), a persistent or chronic cough

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if you get nervous, dizzy, or sleepless, symptoms do not get better within 7 days or are accompanied by fever, cough lasts more than 7 days, comeback, or is accompanied by fever, rash, or persistent headache

These could be signs of a serious condition.

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 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 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 dosage cup for use with this product
- mL = milliliter

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.



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PONCE, PUERTO RICO 00717-1565

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Indication and usage section

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TUFTS PHARMACEUTICAL
SANTA ANA, TUTTILMUTH

4FL OZ (118 mL)

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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

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
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• close cap tightly
• SAVE CAUTION FOR COMPLETE DRUG FACTS

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4FL OZ (118 mL)

Maximum strength
Giltuss Allergy Plus
Cough & Congestion
Alcohol free, Sodium free, sugar free, dye free
Sneezing, runny nose, itchy and watery eyes, cough, stuffy nose, sinus pressure
Tutti Frutti flavor
4 floz 118 ml

GILTUSS ALLERGY PLUS				
chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65852-017	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 10 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	10 mg in 10 mL	
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)		CHLORPHENIRAMINE MALEATE	4 mg in 10 mL	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
CITRIC ACID (UNII: 2968PHW8QP)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
GLYCERIN (UNII: PDC6A3C0OX)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	TUTTI FRUTTI	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:65852-017-04	1 in 1 CARTON	10/02/2018	
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	10/02/2018	

Labeler - Dextrum Laboratories Inc. (007392322)