GILTUSS MULTISYMPTOM COLD AND FLU- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution
Giltuss Pharmaceutical Corp

Giltuss Multi-Symptom Cold & Flu

Drug Facts

Active ingredients (in each 10 mL)

Acetaminophen 650 mg

Chlorpheniramine maleate 4 mg

Dextromethorphan hydrobromide 13 mg

Phenylephrine hydrochloride 10 mg

Purposes

Pain reliever/fever reducer

Antihistamine

Cough Suppressant

Nasal decongestant

Uses

- temporarily relieves:
- minor aches and pains
- headache
- minor sore throat pain
- runny nose
- itchy nose or throat
- sneezing
- itchy watery eyes due to hay fever
- nasal and sinus congestion
- cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if:

- adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use
- if you are allergic to acetaminophen or any inactive ingredient in this product
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 or pharmacist before use if the user has
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- a breathing problem such as chronic bronchitis
- cough that occurs with too much phlegm (mucus)
- chronic cough that lasts such as occurs with smoking, asthma, or emphysema
- trouble urinating due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if the user is
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- **do not exceed recommended dosage**
- marked drowsiness may occur
- excitability may occur, especially in children
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- you get nervousness, dizzyness or sleeplessness
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present

- new symptoms occur
- cough comes back or occurs with fever, rash or headache that lasts.

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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
- do not give more than directed
- use enclosed dosing cup
- keep dosing cup for use with this product
- mL = milliliter

adults and children 12 years and over	10 mL every 4-6 hours, not to exceed 6 doses in 2 hours
children 6 to under 12 years of age	5 mL every 4-6 hours, not to exceed 5 doses in 24 hours
children under 6 years of age	Do not use

Other information
- store at room temperature 15° - 30°C (59° - 86°F)
- close cap tightly
- **SAVE CARTON FOR COMPLETE DRUG FACTS**

Inactive ingredientscitric acid, disodium EDTA, flavor, glycerin, methylparaben, polyethylene glycol, propylene glycol, 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

MAXIMUM STRENGTH

Giltuss® MULTI-SYMPTOM

COLD & FLU

ANALGESIC, ANTITUSSIVE, ANTIHISTAMINE & NASAL DECONGESTANT

ALCOHOL FREE. SODIUM FREE. SUGAR FREE. DYE FREE

RELIEVES
- FEVER, HEADACHE AND BODY ACHES

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

STRAWBERRY FLAVOR

4FL OZ (118 mL)

GILTUSS MULTISYMPTOM COLD AND FLU

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58552-136
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	13 mg in 10 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Product Characteristics

Color	yellow (Light yellow)	**Score**	
Shape		**Size**	
Flavor	STRAWBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-136-04	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 - Giltuss Pharmaceutical Corp (176826592)

Establishment

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc		007392322	manufacture(58552-136)

Revised: 10/2023 Giltuss Pharmaceutical Corp