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

Giltuss Children's Multi-Symptom Cold & Flu

Drug Facts

Active ingredients (in each 5 mL)

Acetaminophen 325 mg

Chlorpheniramine maleate 2 mg

Dextromethorphan HBr 6.5 mg

Phenylephrine HCl 5 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 your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

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

- skin reddening
- blisters
- rash

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

- in a child under 4 years of age
- if your child is 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.
- 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 prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- to make your child sleepy

Ask a doctor or pharmacist before use if the child 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 asthma

Ask a doctor or pharmacist before use if the child 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

Stop use and ask a doctor if

- nervousness, dizzyness or sleeplessness
- pain, nasal congestion, or cough gets worse or lasts more than 5 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- use enclosed dosing cup
- keep dosing cup for use with this product
- mL = milliliter

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

Children's

Giltuss® MULTI-SYMPTOM

COLD & FLU

ANALGESIC, ANTITUSSIVE, ANTIHISTAMINE & NASAL DECONGESTANT

Alcohol Free. Sodium Free. Sugar Free. Dye Free

- FEVER, HEADACHE AND BODY ACHES
- COUGH AND COLD
- STUFFY NOSE
- SNEEZING AND RUNNY NOSE

STRAWBERRY FLAVOR

4FL OZ (118 mL)

GILTUSS CHILDRENS MULTISYMPTOM COLD AND FLU

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58552-137
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE -	CHLORPHENIRAMINE	2 mg

UNII:3U6IO1965U)	MALEATE	in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	6.5 mg in 5 mL
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 5 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:58552-137-04	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(58552-137)