

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

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**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, dizziness 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

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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

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**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 MULTISYMPPTOM COLD AND FLU

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-137
<b>Route of Administration</b>	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
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 5 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	6.5 mg in 5 mL
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

### Product Characteristics

<b>Color</b>	yellow (Light yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### 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)

