

CHILDRENS GILTUSS D- childrens giltuss d syrup
Gil Pharmaceutical Corp

Children's Giltuss-D
ALLERGY & CONGESTION
ANTIHISTAMINIC AND NASAL DECONGESTANT

Drug Facts

Active ingredients (in each 5 mL) Purpose

Chlorpheniramine maleate 1.75 mg Antihistamine

Phenylephrine HCl 5 mg Nasal decongestant

Uses

Temporarily relieves these Symptoms due to hay fever (allergic rhinitis) or other upper-respiratory allergies:

- runny nose
- Sneezing
- Itchy, watery eyes
- nasal congestion
- itching of the nose or throat
- sinus congestion and pressure

Warnings

Do not use

- to sedate a child or to make a child sleepy
- if the child 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.

Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- 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 the child is

- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- may cause drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- if the child gets nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever

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 (1-800-222-1222).

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**

Children under 6 years of age	Consult a Doctor
children 6 to under 12 years of age	5 mL every 4 hours
Adults and children 12 years and over	10 mL every 4 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, Flavor, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Sodium Carboxymethylcellulose, 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.

Label revised: 04/24

**MANUFACTURED FOR
GIL PHARMACEUTICAL CORP.
PONCE, PUERTO RICO 00717-1565**

PRINCIPAL DISPLAY PANEL

Children's Giltuss-D ALLERGY & CONGESTION - NDC 58552-148-04 - Bottle Label

<p>Drug Facts</p>	 <p>NO PSEUDOEPHEDRINE NO PSEUDOEPHEDRINE</p> <p>Children Niños 6-12</p> <p>Children's Giltuss-D ALLERGY & CONGESTION ALERGIA Y CONGESTIÓN</p> <p>Dye Free. Preservative Free. Sodium Free. Sugar Free. Sin Colorantes. Sin Conservativos. Libre de sodio. Sin azúcar.</p> <p>(SNEEZING, RUNNY NOSE, ITCHY & WATERY EYES, ITCHY THROAT OR NOSE, SINUS PRESSURE, STUFFY NOSE) ESNEZIDOS, CORRIENTE NASAL, PÍOZOS Y OJOS LLOROSOS, PÍOZOS DE GARGANTA Y OÍDAS. PRESIÓN POR SINUSITIS, NASAL TAPADA.</p> <p>TUTTI FRUTTI FLAVOR SABOR A TUTTI FRUTTI</p> <p>4FL OZ (118 mL)</p>	<p>When using this product • do not use more than directed • may cause drowsiness • avoid alcoholic beverages • alcohol, sedatives, and tranquilizers may increase drowsiness • avoid alcoholic drinks • be careful when driving a motor vehicle or operating machinery • excitability may occur, especially in children</p>					
<p>Active ingredients (in each 5 mL)</p> <p>Chlorpheniramine maleate, 1.75 mg..... Antihistamine Phenylephrine HCl, 5 mg..... Nasal decongestant</p>		<p>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 (1-800-222-1222).</p>	<p>MANUFACTURED FOR GIL PHARMACEUTICAL CORP. PONCE, PUERTO RICO 00717-1565</p>				
<p>Uses Temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper-respiratory allergies: • runny nose • Sneezing • Itchy, watery eyes • nasal congestion • itching of the nose or throat • sinus congestion and pressure</p>		<p>Stop use and ask a doctor if • if the child gets nervous, dizzy, or sleepless • symptoms do not get better within 7 days or are accompanied by fever</p>					
<p>Warnings Do not use • to sedate a child or to make a child sleepy • if the child 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.</p>		<p>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</p> <table border="1"> <tr> <td>children under 6 years</td> <td>Consult a Doctor</td> </tr> <tr> <td>children 6 to under 12 years</td> <td>5 mL every 4 hours</td> </tr> <tr> <td>Adults and children 12 years and over</td> <td>10 mL every 4 hours</td> </tr> </table>		children under 6 years	Consult a Doctor	children 6 to under 12 years	5 mL every 4 hours
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<p>Ask a doctor before use if the child has: • heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • glaucoma • a breathing problem or persistent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema.</p>	<p>Other information • store at room temperature 15°-30°C (59°-86°F). • close cap tightly • SAVE CARTON FOR COMPLETE DRUG FACTS</p>						
<p>Ask a doctor or pharmacist before use if the child is • taking sedatives or tranquilizers</p>	<p>Inactive ingredients Citric Acid, Flavor, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Sodium Carboxymethylcellulose, Sucralose.</p> <p>Questions or comments? Call 1-787-348-9114, Monday-Friday 9AM-5PM EST. Call your doctor for medical advice in the event of side effects.</p>	<p>For most recent product information, visit www.giltuss.com Label revised: 02/23</p>					

Children's Giltuss-D ALLERGY & CONGESTION - NDC 58552-148-04 - Carton Label



CHILDRENS GILTUSS D

childrens giltuss d syrup

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-148
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	1.75 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	TUTTI FRUTTI	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-148-04	1 in 1 CARTON	04/11/2024	
1		1 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	04/11/2024	

Labeler - Gil Pharmaceutical Corp (176826592)

Revised: 4/2024

Gil Pharmaceutical Corp