

CHILDRENS GILTUSS EX EXPECTORANT- guaifenesin solution
Gil Pharmaceutical Corp

Childrens Giltuss EX Expectorant

Drug Facts

Active ingredients (in each 5 mL)

Guaifenesin, 200 mg

Purpose

Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Ask a doctor before use if your child has

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma or chronic bronchitis

Stop use and ask a doctor if the child has a cough that lasts for more than 1 week, tends to recur, or is accompanied by fever, rash or persistent headache. A persistent cough may be a sign of a serious condition.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not take more than 6 doses in any 24-hour period
- use enclosed dosing cup
- **keep dosage cup for use with this product**
- ml = milliliters

children under 4 years	Consult a doctor
children 4 to under 6 years	2.5 mL every 4 hours
children 6 to under 12 years	5 mL every 4 hours
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, glycerin, methylparaben, natural and artificial flavor, polyethylene glycol, propylparaben, purified water, sodium citrate, 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

giltuss.com

Children 4-12

Children's Giltuss® EX EXPECTORANT

Alcohol Free, Sugar Free. Dye Free, Non Drowsy

CHEST CONGESTION

LIQUIFIES AND LOOSENS PHLEGM

LIQUIFIES AND REMOVES MUCUS

TUTTI FRUTTI FLAVOR

4FL OZ (118 mL)



CHILDRENS GILTUSS EX EXPECTORANT

guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-146
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

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:58552-146-04	1 in 1 CARTON	06/22/2020	
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	06/22/2020	

Labeler - Gil Pharmaceutical Corp (176826592)**Establishment**

Name	Address	ID/FEI	Business Operations
Dextrum Laboratories Inc		007392322	manufacture(58552-146)