GILTUSS TR- guaifenesin,dextromethorphan hbr,phenylephrine hcl tablet
Syntho Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

GILTUSS ® TOTAL RELEASE

EXPECTORANT, ANTITUSSIVE AND NASAL DECONGESTANT>

SUGAR FREE AND PRESERVATIVE FREE

Drug Facts

Active Ingredients (in each tablet)

Guaifenesin 390 mg.

Dextromethorphan HBr 29 mg.

Phenylephrine HCl 10 mg.

Purposes

Expectorant

Antitussive

Nasal Decongestant

Uses

Temporarily relieves the symptoms associated with a cough, the common cold, hay fever, or other upper respiratory allergies.

Helps loosen phlegm (mucus), loosens nasal congestion, thin bronchial secretions, drain bronchial tubes, make coughs more productive, clear stuffy nose, clear nasal passageways, and shrinks swollen membranes.

Warnings

Do not use this product more than the recommended dosage, or 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 are uncertain whether your prescription drug contains an MAOI, ask a health professional.

Ask a doctor before use if you have

• heart disease.

• excessive phlegm (mucus).

• high blood pressure.

• diabetes.

• thyroid disease.

• difficulty in urination due to enlargement of the prostate gland.

• persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema.

Stop use and ask a doctor if:

• nervousness, dizziness, or sleeplessness occurs.

• symptoms are accompanied by fever, rash, persistent headache, or excessive phlegm (mucus).

• cough and congestion do not improve within 7 days or tend to recur.

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use ***. Keep out of the reach of children***. In case of accidental overdose, get medical help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended doses in a 24 hour period

- **Adults and Children 12 years and over:** 1 tablet every 6 to 8 hours. Do not exceed 4 tablets in 24 hours.
- **Children 6 to 12 years:** 1/2 tablet every 6 to 8 hours. Do not exceed 2 tablets in 24 hours.
- **Children under 6 years of age: ask a doctor.**

Other information

• store at room temperature, USP.

• do not use if imprinted safety seal under cap is broken or missing.

Inactive Ingredients

Hydroxypropyl Methylcellulose, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Silicone Dioxide and Stearic Acid.

Questions? Call 787-848-9114

Manufactured for:
GIL PHARMACEUTICAL CORP.,
Ponce, Puerto Rico 00716

Manufactured by:
Syntho Pharmaceuticals, Inc.
Farmingdale, New York (NY) 11735
Label revised: 04/22

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Giltuss ® Total Release - NDC-66576-335-01 - 100's Bottle Label.

GILTUSS TR

guaifenesin,dextromethorphan hbr,phenylephrine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66576-335
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	390 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	29 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	**Score**	no score
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	303;Gil
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66576-335-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/07/2022	

Labeler - Syntho Pharmaceuticals, Inc. (088797407)

Revised: 6/2022

Syntho Pharmaceuticals, Inc.