**GILTUSS TR- guaifenesin,dextromethorphan hbr,phenylephrine hcl tablet**
**Gil Pharmaceutical Corp**

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**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

Label revised: 04/22

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**Giltuss ®Total Release - NDC-58552-335-01 - 100's Bottle Label.**


## Drug Facts

**Active Ingredients** (in each tablet) **Purposes**

Guaifenesin 390 mg. ..... Expectorant

Dextromethorphan HBr 29 mg. ..... Antitussive

Phenylephrine HCl 10 mg. ..... 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.

## Drug Facts (continued)

**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**

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

Label revised: 04/22

## 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 Strearic Acid

## Questions? Call 787-848-9114

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

# GILTUSS TR

guaifenesin,dextromethorphan hbr,phenylephrine hcl tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:58552-335 |
| **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: 3WQ0SDW1A) | |
| **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:58552-335-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 01/07/2022 | |
| **2** | NDC:58552-335-02 | 2 in 1 BLISTER PACK; 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 Drug | M012 | 01/07/2022 | |

## Labeler - Gil Pharmaceutical Corp (176826592)

## Registrant - Syntho Pharmaceuticals, Inc (113616187)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Syntho Pharmaceuticals, Inc. | | 088797407 | manufacture(58552-335) |

Revised: 10/2023 Gil Pharmaceutical Corp