

**GILPHEX- guaifenesin, phenylephrine hcl tablet**  
**Gil Pharmaceutical Corp.**

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**GILPHEX® TOTAL RELEASE**

**EXPECTORANT AND NASAL DECONGESTANT**

**YEAST FREE**

**SODIUM FREE**

**GLUTEN FREE**

**PRESERVATIVE FREE**

**SUGAR FREE**

***Drug Facts***

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

Guaifenesin 390 mg  
Phenylephrine HCl 10 mg

***Purposes***

Expectorant  
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, 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 4 hours. Do not exceed 6 tablets in 24 hours.
- **Children 6 to 12 years:** 1/2 tablet every 4 hours. Do not exceed 3 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, Stearic Acid.

## Questions? Call 787-848-9114

### Manufactured for:

GIL PHARMACEUTICAL CORP.

Ponce, Puerto Rico 00716

Revised Label: 03/22

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

### Gilphex<sup>®</sup> Total Release - NDC-58552-336-01 - 100's Bottle Label

**GIL** PHARMACEUTICAL  
100 Tablets  
MANUFACTURED FOR:  
GIL PHARMACEUTICAL CORP.  
PONCE, PUERTO RICO 00716

**NEW Improved Formula**

**GILPHEX<sup>®</sup>**  
NDC: 58552-336-01

**TOTAL RELEASE**  
EXPECTORANT AND  
NASAL DECONGESTANT

**YEAST FREE, SODIUM FREE, GLUTEN FREE,  
PRESERVATIVE FREE AND SUGAR FREE**

**Each scored tablet contains:**  
Guaifenesin 390 mg  
Phenylephrine Hcl 10 mg

Drug Facts	
<b>Active Ingredients</b> (in each tablet)	<b>Purposes</b>
Guaifenesin 390 mg.....	Expectorant
Phenylephrine Hcl 10 mg .....	Nasal Decongestant
<b>Uses</b>	
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	

Drug Facts (continued)	
<b>Stop use and ask a doctor if</b> • 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 <b>These could be signs of a serious condition.</b>	
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bronchial tubes, make coughs more productive, clear stuffy nose, clear nasal passageways, and shrinks swollen membranes.

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PEEL HERE FOR MORE INFORMATION



Revised Label 03-22

**Other information**

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**Inactive Ingredients**

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GIL PHARMACEUTICAL CORP.  
Ponce, Puerto Rico 00716

**GILPHEX**

guaifenesin, phenylephrine hcl tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-336
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	390 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	

<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	304;Gil
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-336-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2022	
2	NDC:58552-336-02	2 in 1 BLISTER PACK; Type 0: Not a Combination Product	05/05/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/05/2022	

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

**Registrant** - Syntho Pharmaceuticals, Inc. (113616187)

### Establishment

Name	Address	ID/FEI	Business Operations
Syntho Pharmaceuticals, Inc.		088797407	manufacture(58552-336)

Revised: 10/2025

Gil Pharmaceutical Corp.