

GILPHEX- guaifenesin, phenylephrine hcl tablet
Gil Pharmaceutical Corp.

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[®] Total Release - NDC-58552-336-01 - 100's Bottle Label

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

100 Tablets

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

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

NEW Improved Formula

GILPHEX[®]
TOTAL RELEASE
**NASAL DECONGESTANT AND
EXPECTORANT**

NDC: 58552-336-01

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

Uses
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Helps loosen phlegm (mucus), loosens nasal congestion. thin bronchial secretions. drain

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

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PEEL HERE FOR MORE INFORMATION



Revised Label 03-22

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GIL PHARMACEUTICAL CORP.
Ponce, Puerto Rico 00716

GILPHEX

guaifenesin, phenylephrine hcl tablet

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	390 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	CAPSULE	Size	8mm
Flavor		Imprint Code	304;Gil
Contains			

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: 10/2023

Gil Pharmaceutical Corp.