# GILPHEX TR- guaifenes in and phenylephrine hcl tablet, film coated Gil Pharmaceutical Corp

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.

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4062-Gil

### **Drug Facts**

## Active ingredient (in each tablet)

Guaifenesin 388 mg

Phenylephrine HCl 10 mg

#### Purpose

**Expectorant** 

Nasal Decongestant

#### Uses

temporarily relieves these 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
- clears stuffy nose
- clear nasal passageways
- shrinks swollen membranes

**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

Croscarmellose Sodium, Hypromellose, Lactose, Magnesium Silicate, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Mineral Oil, Polyethylene Glycol, Polyvinylpyrrolidone, Silica, Sodium Lauryl Sulfate, Stearic Acid, Titanium Dioxide and Triacetin.

## Questions?

Call 787-848-9114

Manufactured for:

GIL PHARMACEUTICAL CORP.,

Ponce, Puerto Rico 00716

#### **GILPHEX TR**

Guaifenecin, Phenylephrine

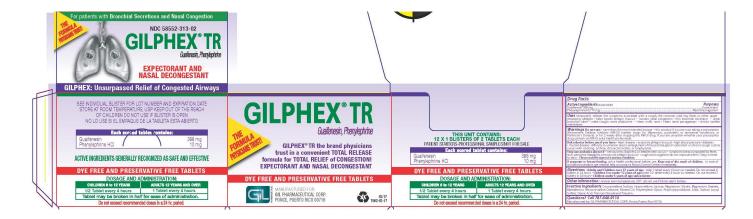
GILPHEX® TR the brand physicians trust in a convenient TOTAL RELEASE formula for TOTAL RELIEF of CONGESTION! EXPECTORANT AND NASAL DECONGESTANT

DYE FREE AND PRESERVATIVE FREE TABLETS

MANUFACTURED FOR:

GIL PHARMACEUTICAL CORP.

PONCE, PUERTO RICO 00716



## **GILPHEX TR**

guaifenesin and phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-313
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	388 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
LACTOSE (UNII: J2B2A4N98G)		
TALC (UNII: 7SEV7J4R1U)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
PO VIDONE K30 (UNII: U725QWY32X)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
TRIACETIN (UNII: XHX3C3X673)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		

Product Characteristics			
Color	white	Score	2 pieces
Shape	OVAL	Size	19 mm

Flavor	Imprint Code	GIL;GIL;304;304
Contains		

	Packaging				
1	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
	NDC:58552-313-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2011		
:	NDC:58552-313-02	12 in 1 CARTON	07/15/2011		
:	2	2 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/12/2008	

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

Revised: 12/2020 Gil Pharmaceutical Corp