

# **GILTUSS SINUS AND CHEST CONGESTION- guaifenesin, phenylephrine hcl tablet**

**Gil Pharmaceutical Corp**

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**4062- Giltuss Sinus & Chest Congestion Tablets**

## ***Drug Facts***

### ***Active Ingredient (in each tablet)***

Guaifenesin 388 mg

Phenylephrine HCl 10 mg

### ***Purpose***

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
- clears stuffy nose
- clear nasal passageways
- shrinks swollen membranes

### ***Warnings***

#### **Do not use**

- more than the recommended dosage
- this product 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****Other information**

- store at room temperature, USP
- do not use if blister seal is broken

**Inactive ingredients** 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 00717-1565**

giltuss.com

MAXIMUM STRENGTH

**GILTUSS®**

**SINUS & CHEST CONGESTION**

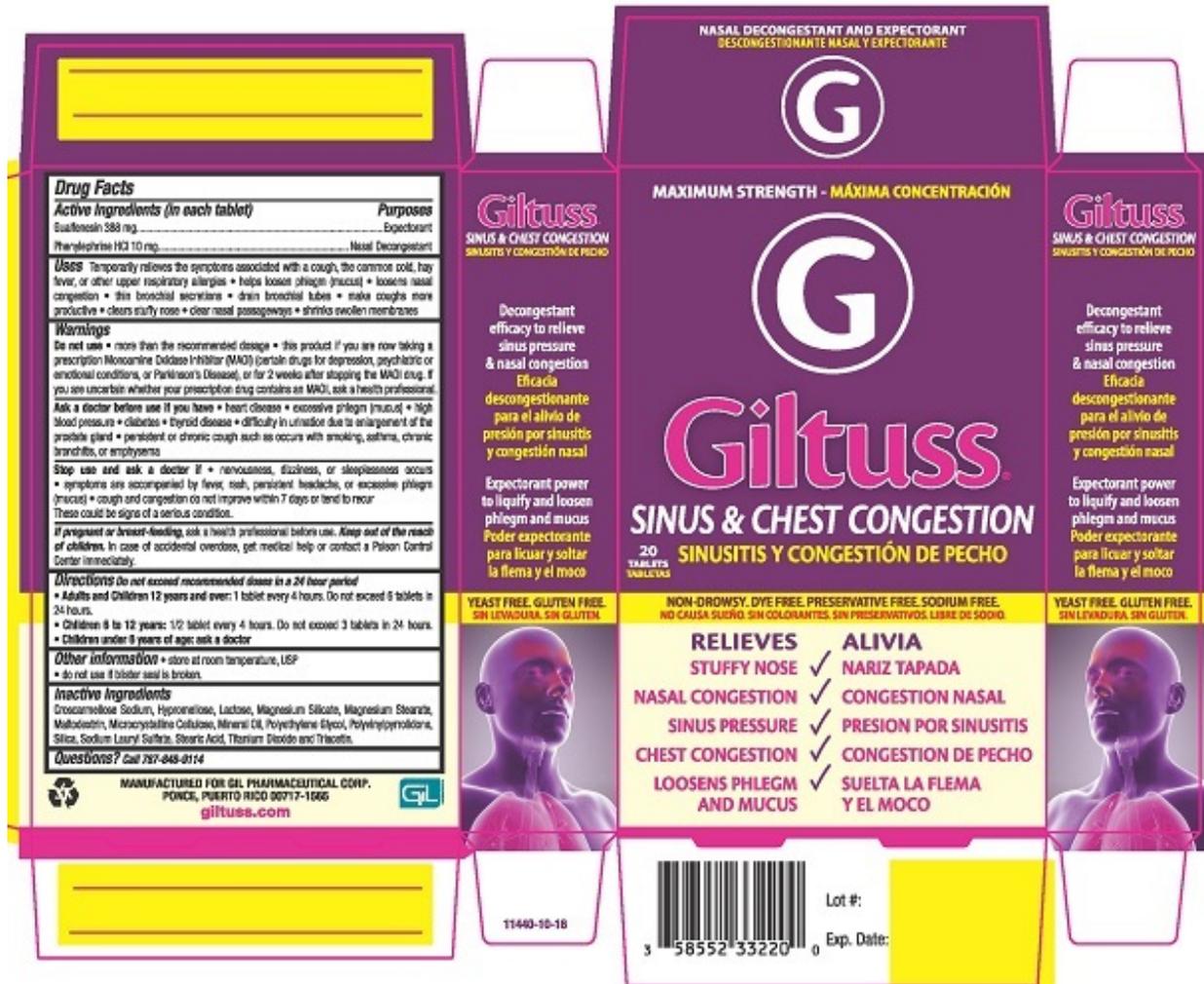
**20 TABLETS**

NON-DROWSY. DYE FREE. PRESERVATIVE .SODIUM FREE

RELIEVES

- STUFFY NOSE
- NASAL CONGESTION
- SINUS PRESSURE

- CHEST CONGESTION
- LOOSENS PHLEGM AND MUCUS



## GILTUSS SINUS AND CHEST CONGESTION

guaifenesin, phenylephrine hcl tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-332
<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	388 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>TRIACETIN</b> (UNII: XHX3C3X673)
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)
<b>LACTOSE</b> (UNII: J2B2A4N98G)
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)
<b>POVIDONE K30</b> (UNII: U725QWY32X)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>TALC</b> (UNII: 7SEV7J4R1U)

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	GILGIL;304304
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-332-20	2 in 1 CARTON	04/01/2021	
1		10 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 Drug	M012	04/01/2021	

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