

**GILTUSS EX MAXIMUM STRENGTH EXPECTORANT- giltuss ex maximum strength expectorant tablet**  
**Gil Pharmaceutical Corp**

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**GILTUSS EX MAXIMUM STRENGTH EXPECTORANT / EXPECTORANTE**  
**Guaifenesin, 1200 mg**

***Drug Facts***

**Active ingredient Purpose (in each extended-release bi-layer tablet)**

Guaifenesin, 1200 mg.....Expectorant

***Uses***

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and helps make cough more productive.

***Warnings***

- Do not use for children under 12 years

**Ask a doctor before use if you have**

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

**Stop use and ask a doctor if**

Cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of serious illness.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of accidental overdose, get medical or professional help or contact a Poison Control Center right away (1-800-222-1222).

***Directions***

- do not crush, chew, or break tablet
- take with a full glass of water
- this product can be administered without regard for the timing of meals
- adults and children 12 years of age and over: 1 or 2 tablets every 12 hours
- Do not exceed 2 tablets in 24 hours
- Do not use for children under 12 years of age

## Other information

- Tamper evident: do not use if the carton is open or if printed seal on bottle is broken or missing
- Store between 20°-25°C (68°-77°F)
- Tamper evident: **Do not use if carton is open or if printed seal under cap is broken or missing.**

**Inactive ingredients:** carbomer homopolymer type B; hypromellose; magnesium stearate; microcrystalline cellulose, sodium starch glycolate.

## Questions or comments?

Call **1-787-848-9114**, Monday-Friday 9AM-5PM EST. Call your doctor for medical advice in the event of side effects.

revised: 08/25

## PRINCIPAL DISPLAY PANEL

### GILTUSS EX MAXIMUM STRENGTH EXPECTORANT / EXPECTORANTE (Guaifenesin, 1200 mg) - NDC 58552-341-14 - 14 Tabs Bottle label

<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose (in each extended-release bi-layer tablet)</b></p> <p>Guaifenesin, 1200 mg Expectorant</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and helps make cough more productive.</li> </ul> <p><b>Warnings</b> • Do not use for children under 12 years</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>• persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema</li> <li>• cough that occurs with too much phlegm (mucus)</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <p>Cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of serious illness.</p> <p><b>If pregnant or breast-feeding</b>, ask a health professional before use. <b>Keep out of reach of children.</b> In case of accidental overdose, get medical or professional help or contact a Poison Control Center right away (1-800-222-1222).</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• do not crush, chew, or break tablet</li> <li>• take with a full glass of water</li> <li>• this product can be administered without regard for the timing of meals</li> <li>• adults and children 12 years and over 1 tablet every 12 hours</li> <li>• Do not exceed 2 tablets in 24 hours</li> <li>• adults and children 12 years of age and over: 1 tablet every 12 hours</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• Do not use if the carton is open or if printed seal on bottle is broken or missing • Store between 20°-25°C (68°-77°F)</li> <li>• Tamper evident: <b>Do not use if carton is open or if printed seal under cap is broken or missing.</b></li> </ul> <p><b>Inactive ingredients:</b> carbomer homopolymer type B; hypromellose; magnesium stearate; microcrystalline cellulose, sodium starch glycolate.</p> <p><b>Questions or comments?</b> Call 1-787-848-9114, Monday-Friday 9AM-5PM EST. Call your doctor for medical advice in the event of side effects.</p> <p>Label revised: 08/25</p>	<p><b>Información del Medicamento</b></p> <p><b>Ingrediente activo (en cada tableta bicapa de liberación prolongada)</b></p> <p>Guaifenesina, 1200mg Expectorante</p> <p><b>Usos</b></p> <ul style="list-style-type: none"> <li>• ayuda a aflojar la flema (mucosa) y las secreciones bronquiales ligeras para liberar las vías bronquiales de mucosa molesta</li> <li>• ayuda a que la tos sea más productiva</li> </ul> <p><b>Advertencias</b> • No usar en niños menores de 12 años Consulte a un médico antes de usarlo si tiene</p> <ul style="list-style-type: none"> <li>• tos persistente o crónica como la tos de fumador, asma, bronquitis crónica o enfisema</li> <li>• tos acompañada de mucha flema (mucosa)</li> </ul> <p><b>Deje de usarlo y consulte a un médico si</b> la tos dura más de 7 días, vuelve o está acompañada de fiebre, irritaciones o dolor de cabeza persistente. Estos podrían ser signos de enfermedad grave.</p> <p><b>Si es una mujer embarazada o lactante</b>, consulte a un médico antes de su uso.</p> <p><b>Mantener fuera del alcance de los niños.</b> En caso de sobredosis accidental, solicite ayuda médica o profesional o contacte inmediatamente a un Centro de Control de Intoxicaciones (1-800-222-1222).</p> <p><b>Instrucciones</b></p> <ul style="list-style-type: none"> <li>• no aplastar, masticar ni romper la tableta</li> <li>• tomar con un vaso de agua</li> <li>• este producto puede ser administrado fuera del horario de las comidas</li> <li>• adultos y niños mayores de 12 años: 1 tableta cada 12 horas</li> <li>• no tomar más de 2 tabletas en 24 horas.</li> <li>• adultos y niños mayores de 12 años: 1 tableta cada 12 horas.</li> </ul> <p><b>Otra información</b></p> <ul style="list-style-type: none"> <li>• No consumir si el cartón fue abierto o si el sello impreso bajo la tapa de la botella está roto o ausente</li> <li>• Almacenar entre 20°-25°C (68°-77°F)</li> </ul>	<p>DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING NO LO USE SI LA TIRILLA DE LA TAPA ESTA ROTA O FALTA</p> <p>SUGAR FREE. ALCOHOL FREE. DYE FREE SIN AZÚCAR. SIN ALCOHOL. SIN COLORANTES.</p> <p><b>G</b></p> <p><b>G</b></p> <p><b>GILTUSS EX</b> <b>MAXIMUM STRENGTH</b> <b>EXPECTORANT / EXPECTORANTE</b> Guaifenesin, 1200 mg</p> <p><b>12 HRS</b></p> <p><b>14</b> EXTENDED RELEASE BI-LAYER TABLETS</p> <p><b>Relieves/Alivia:</b></p> <ul style="list-style-type: none"> <li>CHEST CONGESTION/ CONGESTIÓN DE PECHO</li> <li>LOOSENS AND LIQUIFIES PHLEGM/ SUELVAY LIGEA LA FLEMA</li> <li>LIQUIFIES AND REMOVES MUCUS/ LIGEA Y SAACA EL MOCO</li> <li>EXPULSES PHLEGM AND MUCUS/ EXPULSA LAS FLEMAS Y MOCOS</li> </ul> <p><b>Cont. Información del Medicamento</b></p> <p><b>Ingredientes inactivos:</b> Carbómero homopolímero tipo B, Celulosa microcristalina, Estearato de magnesio, Hipromelosa, Glicolato sódico de almidón.</p> <p><b>¿Tiene preguntas o comentarios?</b> 1-787-848-9114, Lun.-Vi. 9:00 a.m. a 5:00 p.m. EST. En caso de efectos secundarios consulte a su médico. <b>NO USAR SI EL SELLO IMPRESO BAJO LA TAPA ESTÁ ROTO O AUSENTE.</b></p> <p><b>GILTUSS EX</b> <b>MAXIMUM STRENGTH</b> <b>EXPECTORANT / EXPECTORANTE</b> Guaifenesin, 1200 mg</p> <p>SUGAR FREE. ALCOHOL FREE. DYE FREE SIN AZÚCAR. SIN ALCOHOL. SIN COLORANTES.</p>
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MANUFACTURED FOR GIL PHARMACEUTICAL CORP.  
PONCE, PUERTO RICO 00717-1565



giltuss.com

# GILTUSS EX MAXIMUM STRENGTH EXPECTORANT

giltuss ex maximum strength expectorant tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-341
<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	1200 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED)</b> (UNII: Z135WT9208)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	G
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-341-20	1 in 1 CARTON	10/07/2025	
1		14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58552-341-07	1 in 1 CARTON	10/07/2025	
2		7 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	10/07/2025	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Neeyaan, LLC		118819217	manufacture(58552-341)

Revised: 10/2025

Gil Pharmaceutical Corp