

**GILTUSS HBP EX EXPECTORANT- giltuss hbp ex expectorant tablet**  
**Gil Pharmaceutical Corp**

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**Giltuss HBP EX**  
**EXPECTORANT / EXPECTORANTE**  
**Guaifenesin 600 mg**

***Drug Facts***

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

Guaifenesin, 600 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 4 tablets in 24 hours
- children under 12 years of age: do not use

## 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)
- SAVE CARTON FOR COMPLETE DRUG FACTS

**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 HBP EX EXPECTORANT / EXPECTORANTE (Guaifenesin 600 mg) - NDC 58552-340-20 - 20 Tabs Bottle label

<p><b>Drug Facts</b></p> <p><b>Active ingredient Purpose (in each extended-release bi-layer tablet)</b> Guaifenesin, 600 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 Ask a doctor before use if you have</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> 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, ask a health professional before use.</b> 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).</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 of age and over: 1 or 2 tablets every 12 hours</li> <li>• do not exceed 4 tablets in 24 hours</li> <li>• children under 12 years of age: do not use</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• 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)</li> <li>• SAVE CARTON FOR COMPLETE DRUG FACTS</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 style="text-align: right;">Label revised 08/25</p>	<p><b>Información del Medicamento</b></p> <p><b>Ingrediente activo (en cada tableta bicapa de liberación prolongada)</b> Guaifenesina, 600 mg _____ 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. Mantener fuera del alcance de los niños. 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, machucar 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 o 2 tabletas cada 12 horas</li> <li>• no tomar más de 4 tabletas en 24 horas</li> <li>• niños menores de 12 años: no consumir</li> </ul> <p><b>Otra información</b></p> <ul style="list-style-type: none"> <li>• Control de manipulación: no consumir si el cartón fue abierto o si el sello impreso en 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> 12 HRS</p> <p><b>G</b> 12 HRS</p> <p><b>Giltuss HBP EX</b> EXPECTORANT / EXPECTORANTE Guaifenesin 600 mg</p> <p>20 EXTENDED-RELEASE BI-LAYER TABLETS</p> <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. NO USAR SI EL SELLO IMPRESO BAJO LA TAPA ESTÁ ROTO O AUSENTE.</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/ SUelta Y LIQUiA LA FLEMA</li> <li>LIQUIFIES AND REMOVES MUCUS/ LIQUiA Y SACa EL MOCO</li> <li>EXPULS PHLEGM AND MUCUS/ EXPULSA LAS FLEMAs Y MOCOs</li> </ul> <p><b>Giltuss HBP EX</b> EXPECTORANT / EXPECTORANTE Guaifenesin 600 mg</p> <p>SUGAR FREE. ALCOHOL FREE. DYE FREE SIN AZÚCAR. SIN ALCOHOL. SIN COLORANTES.</p> <p>NASAL DECONGESTANT FREE SAFE FOR PEOPLE WITH HIGH BLOOD PRESSURE PROHIBIDA PARA PERSONAS CON PRESIÓN ALTA NO DECONGESTIONANTE NASAL</p>
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## GILTUSS HBP EX EXPECTORANT

giltuss hbp ex expectorant tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-340
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<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:58552-340-20	1 in 1 CARTON	10/07/2025	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58552-340-07	1 in 1 CARTON	10/07/2025	
2		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M012	10/07/2025	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Neeyaan, LLC		118819217	manufacture(58552-340)

Revised: 10/2025

Gil Pharmaceutical Corp