

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

-----  
**GILTUSS 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 EX EXPECTORANT / EXPECTORANTE (Guaifenesin 600 mg) - NDC 58552-338-20 - 20 Tabs Bottle label

**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.

Label revised 08/25

**Información del Medicamento**

**Ingrediente activo (en cada tableta bicapa de liberación prolongada)**  
Guaifenesina, 600 mg \_\_\_\_\_ Expectorante

**Usos**  
• ayuda a aflojar la flema (mucosa) y las secreciones bronquiales ligeras para liberar las vías bronquiales de mucosa molesta  
• ayuda a que la tos sea más productiva

**Advertencias** • *De usar en niños menores de 12 años*  
Consulte a un médico antes de usarlo si tiene  
• tos persistente o crónica como la tos de fumador, asma, bronquitis crónica o enfisema  
• tos acompañada de mucha flema (mucosa)

Deje de usarlo y consulte a un médico si 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.

Si es una mujer embarazada o lactante, 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).

**Instrucciones**  
• no aplastar, masticar ni romper la tableta  
• tomar con un vaso de agua  
• este producto puede ser administrado fuera del horario de los comidas  
• adultos y niños mayores de 12 años: 1 o 2 tabletas cada 12 horas  
• no tomar más de 4 tabletas en 24 horas  
• niños menores de 12 años: no consumir

**Otra información**  
• Control de manipulación: no consumir si el cartón fue abierto o si el sello impreso en la botella está roto o ausente.  
• Almacenar entre 20°-25°C (68° -77°F)

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING  
NO LO USE SI LA TIRILLA DE LA TAPA ESTA ROTA O FALTA

G

12<sup>HRS</sup>

SUGAR FREE. ALCOHOL FREE.  
DYE FREE.  
SIN AZÚCAR. SIN ALCOHOL.  
SIN COLORANTES.

G

## GILTUSS EX

EXPECTORANT / EXPECTORANTE

Guaifenesin 600 mg

12<sup>HRS</sup>

20  
EXTENDED RELEASE  
BI-LAYER TABLETS



**Cont. Información del Medicamento**

**Ingredientes inactivos:** Carbómero homopolímero tipo B, Celulosa microcristalina, Estearato de magnesio, Hipromelosa, Glicolato sódico de almidón.

**¿Tiene preguntas o comentarios?**  
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.



CHEST CONGESTION/  
CONGESTIÓN  
DE PECHO



LOOSENS AND  
LIQUIFIES PHEGM/  
SUELTA Y LIQUA  
LA FLEMA



LIQUIFIES AND  
REMOVES MUCUS/  
LIQUA Y SACA  
EL MOCO



EXPEL PHEGM AND  
MUCUS/EXPELSA  
LAS FLEMAS Y MOCOS

**GILTUSS EX**  
EXPECTORANT / EXPECTORANTE  
Guaifenesin 600 mg

SUGAR FREE. ALCOHOL FREE. DYE FREE  
SIN AZÚCAR. SIN ALCOHOL. SIN COLORANTES.

**GILTUSS EX EXPECTORANT**  
giltuss ex expectorant tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58552-338
<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:58552-338-20	1 in 1 CARTON	10/07/2025	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58552-338-07	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(58552-338)

Revised: 10/2025

Gil Pharmaceutical Corp