

**GILTUSS COUGH AND COLD- dextromethorphan hbr, guaifenesin,
phenylephrine hcl tablet
Gil Pharmaceutical Corp**

4060-Giltuss Cough & Cold Tablets

Drug Facts

Active Ingredients (in each tablet)

Dextromethorphan HBr, 28 mg

Guaifenesin, 388 mg

Phenylephrine HCl, 10 mg

Purposes

Antitussive

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, clear stuffy nose, clear nasal passageways, and shrinks swollen membranes.

Warnings

Do not use 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

- **Adults and Children 12 years and over:** Take 1 tablet every 6 to 8 hours. Do not take more than 4 tablets in a 24 hour period.
- **Children 6 to 12 years of age:** Take 1/2 tablet every 6 to 8 hours. Do not take more than 2 tablets in a 24-hour period.
- **Children under 6 years of age: Consult a physician.**

Other information

- Store at room temperature, USP
- Do not use if blister seal is broken

Inactive ingredients Croscarmellose Sodium, Dicalcium Phosphate, Hypromellose, Magnesium Silicate, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Mineral Oil, Polyvinylpyrrolidone, Silica, Sodium Lauryl Sulfate, Stearic Acid, Titanium Dioxide and Triacetin.

Questions or Comments? Call **787-848-9114**, Mon.-Fri. 9:00 a.m. thru 5:00 p.m. EST. Call your doctor for medical advice in the event of side effects.

MANUFACTURED FOR GIL PHARMACEUTICAL CORP.

PONCE, PUERTO RICO 00717-1565

giltuss.com

MAXIMUM STRENGTH

Giltuss ®

COUGH & COLD

20 TABLETS

SUGAR FREE. DYE FREE. PRESERVATIVE FREE.

RELIEVES

- COUGH AND COLD
- CHEST CONGESTION
- LOOSENS PHLEGM AND MUCUS
- STUFFY NOSE
- NASAL CONGESTION
- SINUS PRESSURE



GILTUSS COUGH AND COLD

dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-331
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	388 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	28 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
LIGHT MINERAL OIL (UNII: N6K5787QVP)
POVIDONE K30 (UNII: U725QWY32X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIACETIN (UNII: XHX3C3X673)
TALC (UNII: 7SEV7J4R1U)
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)

Product Characteristics			
Color	white	Score	2 pieces
Shape	OVAL	Size	19mm
Flavor		Imprint Code	GILGIL;303303
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-331-20	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)

Establishment			
Name	Address	ID/FEI	Business Operations
Ameripharma Labs Limited Liability Company		080033908	manufacture(58552-331) , analysis(58552-331)

Establishment			
Name	Address	ID/FEI	Business Operations
Ameripharma Labs Limited Liability Company		080025541	manufacture(58552-331) , analysis(58552-331)

Establishment			
Name	Address	ID/FEI	Business Operations
Ameripharma Labs Limited Liability Company		117510241	manufacture(58552-331) , analysis(58552-331)

Revised: 10/2025

Gil Pharmaceutical Corp