

GILTUSS TOTAL RELEASE- guaifenesin, dextromethorphan hbr, and phenylephrine hcl tablet, film coated
EXACTUSS TOTAL RELEASE- guaifenesin, dextromethorphan hbr, and phenylephrine hcl tablet, film coated
Gil Pharmaceutical Corp

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

4060-Gil

Drug Facts

Active Ingredients (in each tablet)

Guaifenesin 388 mg

Dextromethorphan HBr 28 mg

Phenylephrine HCl 10 mg

Purposes

Expectorant

Antitussive

Nasal Decongestant

Uses

- temporarily relieves these 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

Do not use this product 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

Do not exceed recommended doses in a 24 hour period

- **Adults and Children 12 years and over:** 1 tablet every 6 to 8 hours. Do not exceed 4 tablets in 24 hours.
- **Children 6 to 12 years:** 1/2 tablet every 6 to 8 hours. Do not exceed 2 tablets in 24 hours.
- **Children under 6 years of age: ask a doctor**

Other Information

- store at room temperature, USP
- do not use if imprinted safety seal under cap is broken or missing.

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?

Call 787-848-9114

Manufactured for:

GIL PHARMACEUTICAL CORP.

Ponce, Puerto Rico 00717-1565

Giltuss TR

NDC 58552-317-02

GILTUSS ®

TOTAL RELEASE

EXPECTORANT, ANTITUSSIVE, AND NASAL DECONGESTANT

SUGAR FREE AND PRESERVATIVE FREE

Each scored tablet contains:

Guaifenesin.....388 mg.

Dextromethorphan HBr.....28 mg.

Phenylephrine HCl.....10 mg.

100 Tablets

MANUFACTURED FOR:

GIL PHARMACEUTICAL CORP.

PONCE, PUERTO RICO 00716

Dextromethorphan, Guaifenesin, Phenylephrine
GILTUSS® TR

THE
FORMULA
 PHYSICIANS TRUST

SUGAR FREE AND PRESERVATIVE FREE TABLETS

GILTUSS TR: Unsurpassed Relief of Cough and Congested Airways

EXPECTORANT, ANTITUSSIVE,
 AND NASAL DECONGESTANT

Dextromethorphan, Guaifenesin, Phenylephrine

GILTUSS® TR

NDC 58552-317-02

For patients with Cough, Bronchial Secretions and Nasal Congestion

For patients with Cough, Bronchial Secretions and Nasal Congestion

NDC 58552-317-02

GILTUSS® TR

Dextromethorphan, Guaifenesin, Phenylephrine

EXPECTORANT, ANTITUSSIVE,
 AND NASAL DECONGESTANT

THE
FORMULA
 PHYSICIANS TRUST

GILTUSS TR: Unsurpassed Relief of Cough and Congested Airways

SEE INDIVIDUAL BLISTER FOR LOT NUMBER AND EXPIRATION DATE
 STORE AT ROOM TEMPERATURE, USP. KEEP OUT OF THE REACH
 OF CHILDREN DO NOT USE IF BLISTER IS OPEN
 NO LO USE SI EL EMPAQUE DE LA TABLETA ESTA ABIERTO

Each scored tablet contains:

Guaifenesin	388 mg
Dextromethorphan HBr	28 mg
Phenylephrine HCl	10 mg

ACTIVE INGREDIENTS GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE
 DOSAGE AND ADMINISTRATION:

CHILDREN 6 to 12 YEARS	ADULTS 12 YEARS AND OVER
1/2 Tablet every 6-8 hours	1 Tablet every 6-8 hours

Tablet may be broken in half for ease of administration.

SUGAR FREE AND PRESERVATIVE FREE TABLETS

Do not exceed recommended doses in a 24 hr. period.

THE
FORMULA
 PHYSICIANS TRUST

GILTUSS® TR

Dextromethorphan, Guaifenesin, Phenylephrine

GILTUSS® TR the brand physicians trust in a convenient
TOTAL RELEASE formula for TOTAL RELIEF of COUGH!
 EXPECTORANT, ANTITUSSIVE AND NASAL DECONGESTANT

SUGAR FREE AND PRESERVATIVE FREE TABLETS



MANUFACTURED FOR:
GIL PHARMACEUTICAL CORP.
 PONCE, PUERTO RICO 00716



03/17
 7702-03-17

THIS UNIT CONTAINS:
12 X 1 BLISTERS OF 2 TABLETS EACH
 PATIENT STARTERS-PROFESSIONAL SAMPLES/NOT FOR SALE

Each scored tablet contains:

Guaifenesin	388 mg
Dextromethorphan HBr	28 mg
Phenylephrine HCl	10 mg

DOSAGE AND ADMINISTRATION:

CHILDREN 6 to 12 YEARS	ADULTS 12 YEARS AND OVER
1/2 Tablet every 6-8 hours	1 Tablet every 6-8 hours

Tablet may be broken in half for ease of administration.

Do not exceed recommended doses in a 24 hr. period.

Drug Facts

Active Ingredients (in each tablet)	Purposes
Guaifenesin 388 mg	Expectorant
Dextromethorphan HBr 28 mg	Antitussive
Phenylephrine HCl 10 mg	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 • clears 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 • Adults and Children over 12 years of age: take 1 tablet every 6-8 hours as needed. Do not exceed 4 tablets in 24 hours • Children 6 to under 12 years of age: take 1/2 tablet every 6-8 hours as needed. Do not exceed 2 tablets in 24 hours • Children under 6 years of age: ask a doctor

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 Tracetin.

Questions? Call 787-848-9114

Manufactured for: GIL PHARMACEUTICAL CORP., Ponce, Puerto Rico 00716

Exactuss TR

NDC: 58552-327-01

Exactuss

Total Release

Expectorant, Antitussive, and Nasal Decongestant

Sugar Free and Preservative free

Exactuss TR is the bioequivalent and contains the exact ingredients of Giltuss TR

100 Tablets

Manufactured For

Gil Pharmaceutical Corp.

Ponce, Puerto Rico 00716

NDC: 58552-327-01



Exactuss[®]

TR
TOTAL RELEASE
EXPECTORANT, ANTITUSSIVE,
AND NASAL DECONGESTANT


SUGAR FREE AND PRESERVATIVE FREE

Exactuss[®] TR is the bioequivalent and contains the exact ingredients of Giltuss[®] TR

100 Tablets
MANUFACTURED FOR:
GIL PHARMACEUTICAL CORP.
PONCE, PUERTO RICO 00716



Drug Facts
Active Ingredients (in each tablet) Guafenesin 388 mg.....Expectorant Dextromethorphan HBr 28 mg.....Antitussive Phenylephrine HCl 10 mg.....Nasal Decongestant
Purposes 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.
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 this product 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



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PEEL HERE FOR MORE INFORMATION

Drug Facts (continued)
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 6 to 8 hours. Do not exceed 4 tablets in 24 hours. • Children 6 to 12 years: 1/2 tablet every 6 to 8 hours. Do not exceed 2 tablets in 24 hours. • Children under 6 years: ask a doctor
Other information • store at room temperature, USP • do not use if imprinted safety seal under cap is broken or missing.
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? Call 787-848-9114 Manufactured for: GIL PHARMACEUTICAL CORP. Ponce, Puerto Rico 00716

GILTUSS TOTAL RELEASE

guaifenesin, dextromethorphan hbr, and phenylephrine hcl tablet, film coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58552-317

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	15mm
Flavor		Imprint Code	GIL;GIL;303;303
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-317-02	12 in 1 CARTON	07/15/2011	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:58552-317-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2011	11/30/2020

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part341	10/19/2009	

EXACTUSS TOTAL RELEASE

guaifenesin, dextromethorphan hbr, and phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58552-327
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TALC (UNII: 7SEV7J4R1U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	15mm
Flavor		Imprint Code	GIL;GIL;303;303
Contains			

Packaging

Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58552-327-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2011	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	10/19/2009		

Labeler - Gil Pharmaceutical Corp (176826592)

Revised: 8/2021

Gil Pharmaceutical Corp