

**IGUALTUSS- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid**  
**Alternative Pharmacal Corporation**

*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.*

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<b>Active Ingredients (in each 5 mL tsp.)</b>	<b>Purpose</b>
Dextromethorphan HBr ..... 28 mg .....	Cough Suppressant
Guaifenesin ..... 388 mg .....	Expectorant
Phenylephrine HCl ..... 10 mg .....	Nasal Decongestant

**Purpose**

Cough Suppressant  
Expectorant  
Nasal Decongestant

**Warnings**

**Do not use** 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 do not know if you are taking a prescription drug that contains an MAOI; ask your doctor or pharmacist before taking this product.

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of prostate gland
- a cough with too much phlegm (mucus)
- a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Ask a doctor before use if you are** taking sedatives, tranquilizers or drugs for depression or MAOI drugs.

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- cough lasts for more than 7 days, comes back or occurs with a fever, rash or headache that lasts. These could be signs of serious condition.

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

**Keep out of reach of children.** In case of accidental overdose, seek advice of a doctor or contact a Poison Control Center right away.

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritations as may occur with the common cold or inhaled irritants
- helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive
- temporarily relieves nasal congestion due to the common cold.

**Directions** Do not exceed more than 4 doses in 24 hours.

Adults and children over 12 years of age

take 1 teaspoonful (5 mL) every 6-8 hours

Children 6 to under 12 years of age

take 1/2 teaspoonful (2.5 mL) every 6-8 hours

Children under 6 years of age

consult a doctor before use

**Inactive ingredients:** Citric acid, FD&C Yellow #6, glycerin, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose

**Questions or comments?** 1-786-507-1566

Monday-Friday 9:00AM -5:00PM

NDC 53163-106-16

# Igualtuss

**Drugs Facts**

**Active ingredients (in each 5 mL tsp.)**      **Purpose**

Dextromethorphan HBr, USP . . . . . 28mg . . . . . Cough Suppressant

Guaifenesin, USP . . . . . 388mg . . . . . Expectorant

Phenylephrine HCl, USP . . . . . 10 mg . . . . . Nasal Decongestant

**Uses** ▪ temporary relieves cough due to minor throat and bronchial irritations as may occur with the common cold or inhaled irritants ▪ helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive ▪ temporarily relieves nasal congestion due to the common cold

**Warnings** ▪ **Do not use** if you are now taking a 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 do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have** ▪ heart disease ▪ high blood pressure ▪ thyroid disease ▪ diabetes ▪ difficulty in urination due to enlargement of prostate gland ▪ a cough with too much phlegm (mucus) ▪ a persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Ask a doctor before use if you are** taking sedatives, tranquilizers or drugs for depression or MAOI drugs.

• Cough Suppressant

• Expectorant

• Nasal Decongestant

Contains the same active ingredients Giltuss® New Improved Formula†

Alternative  
Pharmaceutical  
Corporation

Manufactured For:  
Alternative Pharmacal Corp.  
Miami, FL 33147  
www.alternativepharmaceutical.com

Grape Flavor

Sugar FREE  
Alcohol FREE

**Drugs Facts (Continued)**

**Stop use and ask a doctor if** ▪ nervousness, dizziness, or sleeplessness occur ▪ cough lasts for more than 7 days, comes back or occurs with a fever, rash or headache that lasts. These could be signs of a serious condition.

**If pregnant or breast-feeding**, ask a doctor before use

**Keep out of the reach of children.** In case of accidental overdose, seek advice of a doctor or contact a Poison Control Center right away.

**Directions** Do not exceed 4 doses in 24 hours.

Adults and children over 12 years of age	take 1 teaspoonful (5 mL) every 6-8 hours
Children 6 to under 12 years of age	take 1/2 teaspoonful (2.5 mL) every 6-8 hours
Children under 6 years of age	consult a doctor before use

**Other information** ▪ store at room temperature 15° - 30°C (59° - 86°F).

**Tamper Evident Feature:** Do not use if seal under cap (or cello-band over cap) is torn, broken or missing.

**Pharmacist-** Preserve and dispense in tight-light resistant container with a child resistant cap as defined in the USP.

**Inactive ingredients** Citric acid, FD&C yellow #6, glycerin, L-menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, and sucralose.

**Questions or comments?** 1-786-507-1566  
Monday-Friday 9:00am-5:00pm  
**Manufactured For:** Alternative Pharmacal Corporation, Miami, FL 33147  
www.alternativepharmaceutical.com

**THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING**

3 53163 10616 5

16 fl. oz. (473 mL)

IGUALTUSS			
dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid			
Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53163-106
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	28 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	388 mg in 5 mL	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 5 mL	
Inactive Ingredients			

Ingredient Name	Strength
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MENTHOL (UNII: L7T10EIP3A)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	grape	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53163-106-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2014	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2014	

**Labeler** - Alternative Pharmacal Corporation (078528214)

Revised: 12/2020

Alternative Pharmacal Corporation