

IGUALTUSS- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Alternative Pharmacal Corporation

Alt-Igualtuss 106

Active Ingredients (in each 5 mL tsp.)	Purpose
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
hours

take 1 teaspoonful (5 mL) every 6-8

Children 6 to under 12 years of age
6-8 hours

take 1/2 teaspoonful (2.5 mL) every

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

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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 Giluss® New Improved Formula†

Alternative Pharmaceutical Corporation

Manufactured For:
Alternative Pharmaceutical 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 Pharmaceutical Corporation, Miami, FL 33147
www.alternativepharmaceutical.com

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING



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16 fl. oz. (473 mL)

IGUALTUSS

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53163-106
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (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 Drug	M012	03/01/2014	

Labeler - Alternative Pharmacal Corporation (078528214)