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.

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 smopking, 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 releives nasal congestion due to the common cold.

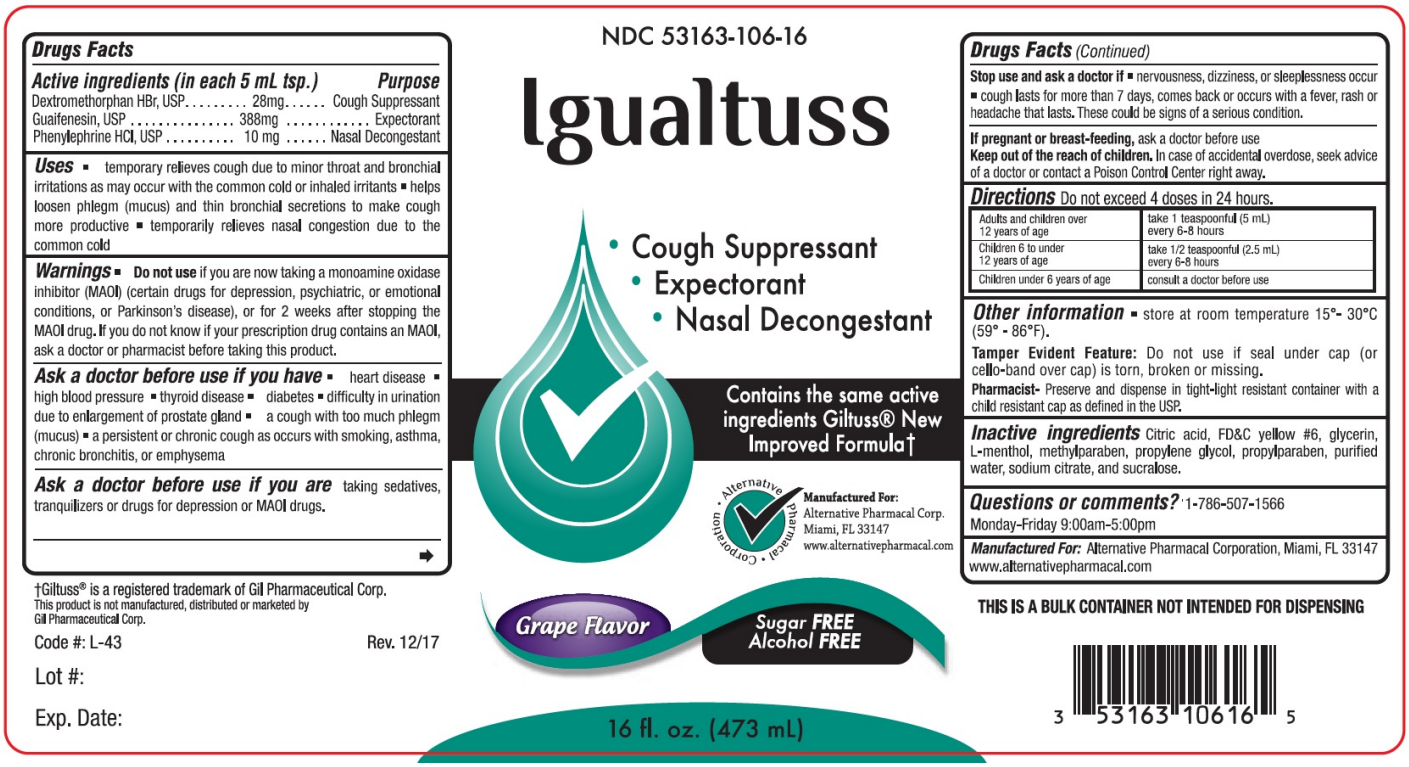
Directions Do not exceed more than 4 doses in 24 hours.

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



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**
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 final	part341	03/01/2014	

Labeler - Alternative Pharmacal Corporation (078528214)

Revised: 12/2020 Alternative Pharmacal Corporation