G-TUSS-NL PED- dextromethorphan hydrobromide, guaifenesin, and pseudoephedrine hydrochloride liquid
McLaren Medical

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.

G-Tuss-NL Ped

Drug Facts

Active Ingredients (in each 5 mL, teaspoonful)	***Purpose***
Guaifenesin 50 mg	Expectorant
Dextromethorphan HBr 5 mg	Cough Suppressant
Pseudoephedrine HCI 15 mg	Nasal Decongestant

Indications

- For the temporary relief of nasal congestion due to the common cold, hay fever or other upper respiratory allergies (allergic rhinitis).
- Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.
- Temporarily controls cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants.
- Temporarily helps you cough less.

Warnings

- **Do not exceed recommended dosage**.
  If nervousness, dizziness or sleeplessness occurs, discontinue use and consult a doctor.
- If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor.

- Do not give this product to a child who has heart disease, high blood pressure, thyroid disease, or diabetes, unless directed by a doctor.
- Do not use in a child who is 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 your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

- A persistent cough may be the sign of a serious condition. If cough persists for more than 1 week, tends to recur or is accompanied by a fever, rash or persistent headache, consult a doctor.

- Do not take this product for persistent or chronic cough such as occurs with asthma or emphysema or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

- **In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately**.

- **Keep this and all drugs out of the reach of children**.

Directions

Do not take more than 6 doses in any 24-hour period.

Children 6 to under 12 years of age	2 teaspoonfuls (10 mL) every 4 hours
Children 2 to under 6 years of age	1 teaspoonful (5 mL) every 4 hours
Children under 2 years of age	Consult a doctor

Inactive Ingredients

Citric Acid, Grape Flavor, Propylene Glycol, Purified Water, Saccharine Sodium, Sodium Benzoate, Sorbitol, Sucralose.

Other Information

Store at 20°-25°C (68°-77°F)

Tamper evident by seal under cap. Do not use if the seal is broken or missing.

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC-43913-406-16

G-Tuss-NL Ped

Cough Suppressant, Expectorant & Nasal Decongestant

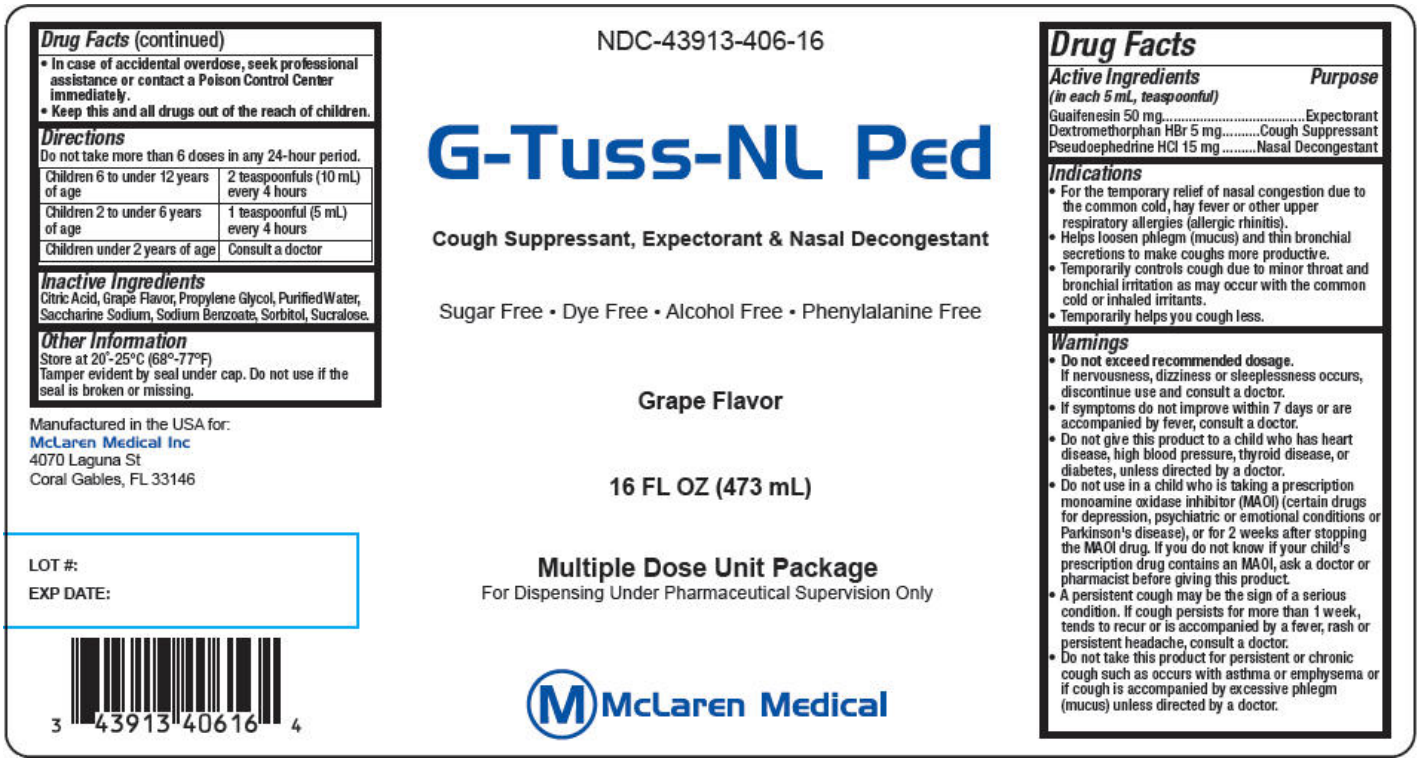
Sugar Free • Dye Free • Alcohol Free • Phenylalanine Free

Grape Flavor

16 FL OZ (473 mL)

Multiple Dose Unit Package
For Dispensing Under Pharmaceutical Supervision Only

McLaren Medical



G-TUSS-NL PED

dextromethorphan hydrobromide, guaifenesin, and pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43913-406
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	5 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	50 mg in 5 mL
Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Benzoate (UNII: OJ245FE5EU)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Sorbitol (UNII: 506T60A25R)	
Saccharin Sodium (UNII: SB8ZUX40TY)	
Sucralose (UNII: 96K6UQ3ZD4)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43913-406-16	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	02/11/2014	

Labeler - McLaren Medical (013770591)

Registrant - davAgen Pharmaceutical, LLC (967545935)

Establishment

Name	Address	ID/FEI	Business Operations
davAgen Pharmaceutical, LLC		967545935	MANUFACTURE(43913-406) , PACK(43913-406) , LABEL(43913-406) , ANALYSIS(43913-406)

Revised: 4/2014 McLaren Medical