TUSSIN CF- dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride liquid
davAgen Pharmaceutical, LLC

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.

Tussin CF

Active ingredients (in each 5 mL tsp):	*Purpose*
Dextromethorphan HBr, USP 10 mg	Cough suppressant
Guaifenesin, USP 100 mg	Expectorant
Phenylephrine HCl, USP 5 mg	Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes
- temporarily relieves these symptoms occurring with a cold:
  - nasal congestion
  - cough due to minor throat and bronchial irritation

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 your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have cough that occurs with too much phlegm (mucus) or a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema, trouble urinating due to an enlarged prostate gland

Do not exceed recommended dose

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center

Other information

Each tsp contains: sodium 6 mg. Store at 20°-25°C (68°-77°F), Do not refrigerate.

Dosage cup provided.

Inactive ingredients

citric acid, FD & C Red # 40, flavor, glycerin, menthol, propylene glycol, purified water, saccharine sodium, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Directions

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

- this adult product is not intended for use in children under 12 years of age
- mL = milliliter; tsp = teaspoonful

age	dose
adults and children 12 years and over	10 mL (2 tsp) every 4 hours
children under 12 years	do not use

Manufactured by:
davAgen
Pharmaceutical LLC
Somerset, NJ 08873

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

davAgen
pharmaceutical

NDC 76140-105-08

Adults & Children Ages 12 & Older

Tussin CF

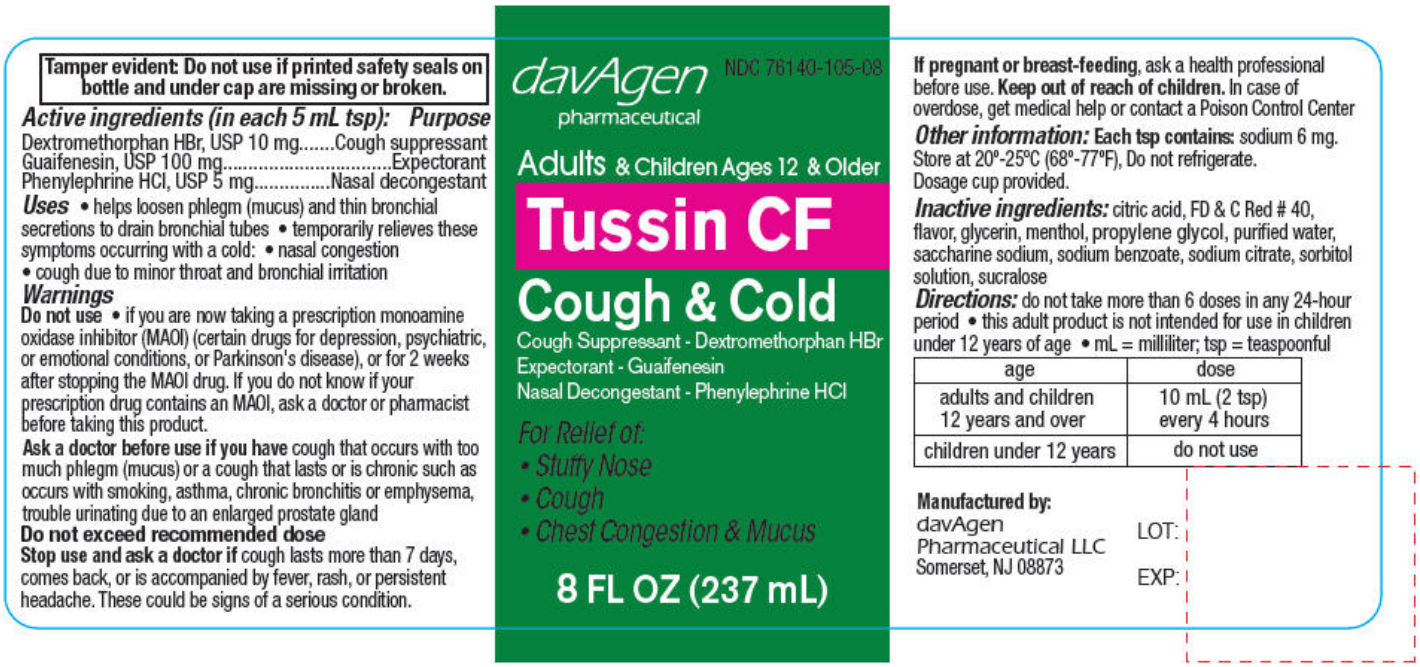
Cough & Cold

Cough Suppressant - Dextromethorphan HBr
Expectorant - Guaifenesin
Nasal Decongestant - Phenylephrine HCl

For Relief of:

- *Stuffy Nose*
- *Cough*
- *Chest Congestion & Mucus*

8 FL OZ (237 mL)



TUSSIN CF

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76140-105
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 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)	
FD&C Red NO. 40 (UNII: WZB9127XOA)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Glycerin (UNII: PDC6A3C0OX)	
Sodium Citrate (UNII: 1Q73Q2JULR)	
Menthol (UNII: L7T10EIP3A)	
Water (UNII: 059QF0KO0R)	

Product Characteristics			
Color	RED	Score	
Shape		Size	
Flavor	CHERRY, FRUIT, MENTHOL	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76140-105-08	1 in 1 CARTON		
1		236 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/10/2013	

Labeler - davAgen Pharmaceutical, LLC (967545935)

Establishment

Name	Address	ID/FEI	Business Operations
davAgen Pharmaceutical, LLC		967545935	MANUFACTURE(76140-105) , PACK(76140-105) , LABEL(76140-105) , ANALYSIS(76140-105)

Revised: 12/2013 davAgen Pharmaceutical, LLC