

TUSSIN CF - dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Kareway Product, Inc.

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.

Drug Facts

Active ingredients

(in each 5mL tsp)

Dextromethorphan HBr, USP 10mg

Guaifenesin, USP 100mg

Phenylephrine HCl, USP 5mg

Purpose

Cough suppressant

Expectorant

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

When using this product do not use more than directed.

Stop use and ask a doctor if,

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- 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 right away.

Directions

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

Age	Dose
adults and children 12 years and over	2 tsp every 4 hours
children 6 years to under 12 years	1 tsp every 4 hours
children 2 years to under 6 years	1/2 tsp every 4 hours
children under 2 years	ask a doctor

Other information

- each teaspoon contains: **sodium 1mg**
- store at 20-25°C (68-77°F)
- alcohol-free
- dosage cup provided
- not a USP elixir

Inactive ingredients

cherry flavor, citric acid, FD and C red no. 40, glycerin, sucrose, sucralose, menthol, propylene glycol, purified water, xanthan gum, polysorbate, sorbitol solution, sodium benzoate

Package label

Tussin DM



TUSSIN CF

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67510-0506

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
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCROSE (UNII: C151H8M554)	
MENTHOL (UNII: L7T10EIP3A)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0506-4	1 in 1 BOX		
1		120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/26/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 8/2011

Kareway Product, Inc.