TUSSIN DM - dextromethorphan hbr, guaifenes in 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

Purpose

Cough suppressant Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

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

- a cough that occurs with too much phlegm (mucus)
- a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor ir

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

- store at 20-25°C (68-77°F)
- alcohol-free
- dosage cup provided

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

<section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><section-header><text><text><text><text></text></text></text></text></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header></section-header>	Superior of the second se	<section-header><section-header><section-header><section-header></section-header></section-header></section-header></section-header>	Pure-Aid Compore to active ingredients in Robitussin Cough C	
TUSSIN DM dextromethorphan hbr, guaifenesin liqu	iid			

Product Information

Product T ype

HUMAN OTC DRUG

Item Code (Source)

NDC:67510-0527

ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients Ingredient Name Strength CHERRY (UNII: BUC5I9595W) CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) FD&C RED NO. 40 (UNII: WZB9127XOA) GLYCERIN (UNII: PDC6A3C0OX) SUCROSE (UNII: C151H8 M554) **SUCRALOSE** (UNII: 96K6UQ3ZD4) MENTHOL (UNII: L7T10EIP3A) **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) WATER (UNII: 059QF0KO0R) XANTHAN GUM (UNII: TTV12P4NEE) POLYSORBATE 20 (UNII: 7T1F30V5YH) SORBITOL (UNII: 506T60A25R) SODIUM BENZOATE (UNII: OJ245FE5EU)

Packaging					
#	Item Code	Package Description	Marketin	g Start Date	Marketing End Date
1 NI	DC:67510-0527-4	1 in 1 BOX			
1		120 mL in 1 BOTTLE			
Ma	rketing Infor	mation			
	rketing Infor •keting Category	r mation Application Number or Monogra	aph Citation	Marketing Start D	Date Marketing End Date

Labeler - Kareway Product, Inc. (121840057)

Revised: 8/2011

Kareway Product, Inc.