

GERI-TUSSIN DM- dextromethorphan hbr, guaifenesin liquid
Geri-Care Pharmaceuticals, Corp

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.

per 5 mL teaspoonful

Dextromethorphan HBr - 10 mg

Guaifenesin - 100 mg

Purpose

□Cough Suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus)
- helps thin bronchial secretions to make coughs more productive

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.

Do not use if you have ever had an allergic reaction to any of the ingredients in this product.

Ask a doctor before use if you have

- a cough 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 if**

cough lasts more than 7 days, comes back or is accompanied by fever, rash, or headache that lasts. 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

- take every 4 hours as needed, or as directed by a doctor
- do not take more than 6 doses in 24 hours
- do not exceed recommended dose

Adults and children 12 years and over



2 teaspoonfuls (10 mL)

Children under 12 years

do not use

Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, sucrose COMPARE TO THE ACTIVE INGREDIENTS OF

Distributed by: GERI-CARE PHARMACEUTICALS CORP. 1650 63rd Street Brooklyn, NY 11204

<p>Drug Facts</p> <p>Active ingredient (per 5mL teaspoonful) Purposes Dextromethorphan HBr, USP 10 mg.....Cough suppressant Guaifenesin, USP 100 mg.....Expectorant</p> <p>Uses • temporarily relieves cough due to minor throat and bronchial irritation • helps loosen phlegm (mucus) • helps thin bronchial secretions to make coughs more productive</p> <p>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.</p> <p>Do not use if you have ever had an allergic reaction to any of the ingredients in this product.</p> <p>Ask a doctor before use if you have • a cough with too much phlegm (mucus) • a cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis or emphysema</p> <p>Stop use and ask a doctor if cough lasts more than 7 days, comes back or is accompanied by fever, rash, or headache that lasts. These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ▶</p>	 <p>NDC 57896-661-16</p> <p>GERI - TUSSIN DM</p> <p>COUGH SUPPRESSANT • EXPECTORANT</p> <p>• CONTROLS COUGH</p> <p>• LOOSENS & RELIEVES CHEST CONGESTION</p> <p>COMPARE TO THE ACTIVE INGREDIENTS OF ROBITUSSIN® DM*</p> <p>ALCOHOL FREE</p> <p>COUGH FORMULA FOR ADULTS & CHILDREN 12 YEARS AND OVER</p> <p>PACKAGE NOT CHILD RESISTANT</p> <p>16 FL OZ (473 mL)</p>	<p>Drug Facts (continue)</p> <p>Directions</p> <ul style="list-style-type: none"> • take every 4 hours as needed, or as directed by a doctor • do not take more than 6 doses in 24 hours • do not exceed recommended dose <table border="1"> <tr> <td>Adults and children 12 years and over</td> <td>2 teaspoonfuls (10 mL)</td> </tr> <tr> <td>Children under 12 years</td> <td>do not use</td> </tr> </table> <p>Other information</p> <ul style="list-style-type: none"> • each teaspoonful (5 mL) contains: sodium 2 mg • store at room temperature 15°- 30°C (59°-86°F) • protect from freezing • do not refrigerate • protect from light • TAMPER-EVIDENT: Do not use if foil seal over bottle opening is torn broken or missing. <p>Inactive ingredients: artificial and natural cherry flavor, citric acid, FD&C Red #40, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose, sucrose</p> <p><small>*This product is not manufactured or distributed by the owner of the registered trademark Robitussin® DM.</small></p> <p>For Institutional Use Distributed by: GERI-CARE PHARMACEUTICALS CORP. 1650 63rd Street Brooklyn, NY 11204</p>  <p>Code# L151 REV0419</p> <p>Lot#</p> <p>Exp. Date:</p>	Adults and children 12 years and over	2 teaspoonfuls (10 mL)	Children under 12 years	do not use
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GERI-TUSSIN DM

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-661
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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

SUCROSE (UNII: C151H8M554)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-661-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2019	

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Revised: 6/2019

Geri-Care Pharmaceuticals, Corp