

GUAIASORB DM- dextromethorphan hbr, guaifenesin liquid
Ger-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.

Active ingredients (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 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 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

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

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, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

NDC 57896-736-04



GUAIASORB DM

SUGAR FREE • ALCOHOL FREE

EXPECTORANT COUGH SUPPRESSANT

Loosens and relieves chest congestion
Controls Coughs

CLEAR FORMULA

4 FL OZ (118 mL)

Drug Facts

Active ingredients (per 5 mL teaspoonful)

Dextromethorphan HBr: 10 mg Cough suppressant
Guaifenesin 100 mg 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.

Ask a doctor before use if 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

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

Adults and children 12 years and over: 2 teaspoonfuls (10 mL)
Children under 12 years: Do not use

Other information

• store at room temperature between 15°-30°C (59°-86°F) • **TAMPER EVIDENT: Do not use this product if breakaway band on cap is broken or missing.**

Inactive ingredients artificial and natural cherry flavor, citric acid, menthol, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate, sucralose

Dist. By: Geri-Care Pharmaceuticals Corp.
1650 63rd Street, Brooklyn, NY 11204

Code # L-9
REV 0519



Lot and Exp

GUAIASORB DM

dextromethorphan hbr, guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-736
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)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:57896-736-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		10/01/2019	

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Revised: 11/2019

Geri-Care Pharmaceuticals, Corp