

**SILTUSSIN DM - guaifenesin and dextromethorphan hydrobromide liquid**  
**Silarx Pharmaceuticals, 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.*

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**Siltussin DM Cough Syrup**

Active Ingredient: Guaifenesin 100 mg (in each 5 mL (teaspoon)(TSP))

Active Ingredient: Dextromethorphan Hydrobromide 10 mg (in each 5 mL (teaspoon)(TSP))

Purpose of Guaifenesin: Expectorant

Purpose of Dextromethorphan Hydrobromide: Cough Suppressant

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation
- helps loosen phlegm (mucus) and 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 you have**

- persistent cough or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema
- cough accompanied by excessive phlegm (mucus)

**Stop use and ask a doctor if**

- cough lasts more than 7 days or occurs with fever, rash, or headaches that lasts. This could be signs of a serious condition
- hypersensitive to any ingredients

**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. **This adult product is not intended for use in children under 12 years of age**

Adults and children 12 years and over	2 teaspoonfuls (TSP) every 4 hours
<b>Children under 12 years</b>	<b>DO NOT USE</b>

## Inactive ingredients

citric acid, FD&C red no. 40, glycerin, menthol, methylparaben, propylene glycol, saccharin sodium, sodium benzoate, strawberry flavor, sucrose, purified water.

## Other information

store at room temperature 20°-25°C (68°-77°F)

**Questions:** 888-974-5279

Manufactured by

Silarx Pharmaceutical Inc,

1033 Stoneleigh Ave.

Carmel, NY 10512

**SILARX**  
NDC 54838-209-40  
**Siltussin-DM**  
Non-Drowsy  
Alcohol-Free  
Expectorant  
Cough Suppressant  
FOR AGES 12 AND OVER  
DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING  
118 mL (4 fl oz)

**Drug Facts**  
**Active ingredients (in each 5 mL (teaspoon) (TSP))**  
Guaifenesin 100 mg ..... Expectorant  
Dextromethorphan Hydrobromide 10 mg ..... Cough Suppressant  
**Purpose**  
Expectorant  
**Uses**  
Temporarily relieves cough due to minor throat and bronchial irritation  
helps loosen phlegm (mucus) and 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 you have**  
persistent cough or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema  
cough accompanied by excessive phlegm (mucus)  
**Stop use and ask a doctor if**  
cough lasts more than 7 days or occurs with fever, rash, or persistent headache. This could be signs of a serious condition  
hypersensitive to any ingredients  
**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.  
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888-974-5279  
Rev. 09/13  
Manufactured by:  
Silarx Pharmaceuticals, Inc.  
1033 Stoneleigh Ave.  
Carmel, NY 10512  
Control # Exp. Date  
54838-209-40

## SILTUSSIN DM

guaifenesin and dextromethorphan hydrobromide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54838-209
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Guaifenesin</b> (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg in 5 mL
<b>Dextromethorphan Hydrobromide</b> (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>anhydrous citric acid</b> (UNII: XF417D3PSL)	
<b>FD&amp;C red no. 40</b> (UNII: WZB9127XOA)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>menthol</b> (UNII: L7T10EIP3A)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>saccharin sodium dihydrate</b> (UNII: SB8ZUX40TY)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>sucrose</b> (UNII: C151H8M554)	
<b>water</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	STRAWBERRY (STRAWBERRY FLAVOR)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54838-209-40	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:54838-209-70	237 mL in 1 BOTTLE, PLASTIC		
3	NDC:54838-209-80	473 mL in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	09/05/1992	

**Labeler** - Silarx Pharmaceuticals, Inc (161630033)

Revised: 6/2014

Silarx Pharmaceuticals, Inc