SILTUSSIN DM- guaifenesin and dextromethorphan hydrobromide liquid
A-S Medication Solutions

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.

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**

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2 teaspoonfuls (TSP)

Adults and children 12 years and over	2 teaspoonfuls (TSP) every 4 hours
Children under 12 years	**DO NOT USE**

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

HOW SUPPLIED

Product: 50090-4225

NDC: 50090-4225-0 118 mL in a BOTTLE, PLASTIC

Guaifenesin and Dextromethorphan Hydrobromide

SILTUSSIN DM

guaifenesin and dextromethorphan hydrobromide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-4225(NDC:54838-209)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	STRAWBERRY (STRAWBERRY FLAVOR)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4225-0	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/27/2019	

Marketing Information

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

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4225)