

SILTUSSIN DM DAS COUGH FORMULA- guaifenesin and dextromethorphan hydrobromide liquid
ALTANTIC BIOLOGICALS 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.

Siltussin DM DAS Cough Formula

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

Active Ingredient: Dextromethorphan HBr 10 mg (in each 5 mL (teaspoonful)(TSP))

Purpose of Guaifenesin: Expectorant

Purpose of Dextromethorphan HBr: Cough Suppressant

Uses

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

- take every 4 hours, 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 (TSP)(10 mL)	
Children under 12 years	DO NOT USE

Other information

store at room temperature between 15°-30°C (59°-86°F)

Inactive ingredients

citric acid, strawberry flavor, glycerin, menthol, methylparaben, propylene glycol, saccharin sodium, sodium benzoate, sorbitol, water.

Questions

1-844-834-0530

* This product is not manufactured or distributed by Whitehall Robins, distributor of Robitussin®-DM.

Manufactured by:
Silarx Pharmaceuticals, Inc.
Carmel, NY 10512

10-1042 Rev. 03/18

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N.E 16TH PLACE

MIAMI, FL 33179

17856-0134-01

Siltussin DM

(Guaifenesin/Dextromethorphan HBr) Cough Suppressant

100mg/10mg/5mL

Delivers 5mL

See package insert for indications and dosage schedule



Store at room temperature between 15°-30°C
(59°-86°F). Expectorant.

Dye free, Alcohol & Sugar free

KEEP OUT OF THE REACH OF CHILDREN

17856-0134-01

Dosage: 100mg/10mg/5mL

Siltussin DM

(Guaifenesin/Dextromethorphan HBr)

Qty: 72 CUPS



GTIN: 00117856013419

S/N: 01108801

Exp: 01/29/21

Lot: 011088

OTC

Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
Miami FL 33179

Rev. 09/19

Call to Reorder: 800.509.7592

**GUAIFENESIN/
DEXTROMETHORPHAN HBr
(SILTUSSIN DM)
100MG/10MG/5ML
EXPECTORANT ORAL LIQUID
SUGAR FREE/ALCOHOL FREE
DELIVERS 5 ML**



17856013401

**DISTRIBUTED BY ATLANTIC
BIOLOGICALS CORP.**

Exp:07/29/2020

Lot#lot1

Mfg:SILARX MFG LOT #2485A
Pkg by UDS

Morrisville, NC 27560

17856-0134-02

**Siltussin DM (Guaifenesin
Dextromethorphan HBr)**

Cough Suppressant

200mg/20mg/10mL

Delivers 10mL

See package insert for indications and dosage schedule



17856013402

Store at room temperature between 15°-30°C
(59°-86°F)

Dye free, Alcohol & Sugar free

KEEP OUT OF THE REACH OF CHILDREN

17856-0134-02

Dosage: 200mg/20mg/10mL

**Siltussin DM (Guaifenesin
Dextromethorphan HBr)**

Qty: 72 CUPS



GTIN: 00117856013426

S/N: 01108701

Exp: 01/29/21

Lot: 011087

OTC

Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev. 09/19

Call to Reorder: 800.509.7592

**GUAIFENESIN/
DEXTROMETHORPHAN HBr
(SILTUSSIN DM)
200MG/20MG/10ML
EXPECTORANT ORAL LIQUID
SUGAR FREE/ALCOHOL FREE
DELIVERS 10ML**



17856013402

**DISTRIBUTED BY ATLANTIC
BIOLOGICALS CORP.**

Exp:07/29/2020

Lot#lot1

Mfg:SILARX MFG LOT#2380A

Pkg by UDS

Morrisville, NC 27560

SILTUSSIN DM DAS COUGH FORMULA

guaifenesin and dextromethorphan hydrobromide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0134(NDC:54838-133)
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)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		Score	
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Shape		Size		
Flavor	STRAWBERRY (strawberry flavor)	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0134-1	72 in 1 BOX, UNIT-DOSE	03/05/2020	
1		5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0134-2	72 in 1 BOX, UNIT-DOSE	03/05/2020	
2		10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL		part341	09/05/1995	

Labeler - ALTANTIC BIOLOGICALS CORP. (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
ALTANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0134) , repack(17856-0134)