

SILTUSSIN SA- guaifenesin liquid
Atlantic Biologicals Corps

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 SA (Guaifenesin Liquid)

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

Purpose: Expectorant

Helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive **Uses**

Warnings

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

if cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition. **Stop use and ask a doctor**

If pregnant or breast-feeding, ask a health professional before use.

. In case of overdose, get medical help or contact a Poison Control Center right away. **Keep out of reach of children**

Directions

- do not take more than 6 doses in any 24-hour period
- repeat dose every 4 hours

adults and children 12 years and over	2-4 teaspoonfuls (TSP)
children under 12 years	DO NOT USE

Store at room temperature 20°-25°C (68°-77°F). . **Other information**

Do not accept if imprinted tamper evident safety seal around cap is broken or missing

Inactive ingredients

citric acid, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, strawberry flavor, glycerin, propylene glycol, saccharin sodium, sodium benzoate, sodium citrate, sorbitol, purified water.

Questions

888-974-5279

SILTUSSIN SA (GUAIFENESIN) LIQUID

**GUAIFENESIN LIQUID
(SILTUSSIN SA)
100MG/5ML
EXPECTORANT ORAL LIQUID
SUGAR FREE/ALCOHOL FREE
DELIVERS 5 ML**



17856011705

**DISTRIBUTED BY ATLANTIC
BIOLOGICALS CORP.**

Exp:07/30/2020
Lot#lot1

Mfg:SILARX MFG LOT#1489A
Pkg by UDS
Morrisville, NC 27560

**GUAIFENESIN LIQUID
(SILTUSSIN SA)
300 MG/15 ML
EXPECTORANT ORAL LIQUID
SUGAR FREE/ALCOHOL FREE
DELIVERS 15 ML**



17856011701

**DISTRIBUTED BY ATLANTIC
BIOLOGICALS CORP.**

Exp:07/30/2020
Lot#lot1

Mfg:SILARX MFG LOT#1547A
Pkg by UDS
Morrisville, NC 27560

**GUAIFENESIN LIQUID
(SILTUSSIN SA)
200 MG/10 ML
EXPECTORANT ORAL LIQUID
SUGAR FREE/ALCOHOL FREE
DELIVERS 10 ML**



17856011702

**DISTRIBUTED BY ATLANTIC
BIOLOGICALS CORP.**

Exp:07/30/2020
Lot#lot1

Mfg:SILARX MFG LOT#1547A
Pkg by UDS
Morrisville, NC 27560

17856-0117-01
GUAIFENESIN
(SILTUSSIN SA)
300MG/15ML
ORAL LIQUID
DELIVERS 15ML



See package insert for indications and dosage schedule

Store at room temperature 20°-25°C (68°-77°F).
EXPECTORANT. SUGAR & ALCOHOL FREE
KEEP THIS AND ALL MEDICATION OUT OF
THE REACH OF CHILDREN



17856-0117-01

Dosage: 300MG/15ML

GUAIFENESIN (SILTUSSIN
SA)

Qty: 50 CUPS



GTIN: 00117856011712

S/N: 01109301

Exp: 01/29/21

Lot: 011093

OTC

Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.
Miami FL 33179

Rev.09/19

Call to Reorder: 800.509.7592

17856-0117-02
GUAIFENESIN
(SILTUSSIN SA)
200MG/10ML
ORAL LIQUID
DELIVERS 10ML



See package insert for indications and dosage schedule



Store at room temperature 20°-25°C (68°-77°F).
EXPECTORANT. SUGAR & ALCOHOL FREE
KEEP THIS AND ALL MEDICATION OUT OF
THE REACH OF CHILDREN

17856-0117-02

Dosage: 200MG/10ML

GUAIFENESIN (SILTUSSIN
SA)

Qty: 72 CUPS



GTIN: 00117856011729

S/N: 01109801

Exp: 01/29/21

Lot: 011098

OTC

Packaged by Unit Dose Solutions
Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.
Miami FL 33179

Rev.09/19

Call to Reorder: 800.509.7592

17856-0117-05
GUAIFENESIN
(SILTUSSIN SA)
100MG/5ML
ORAL LIQUID
DELIVERS 5ML



See package insert for indications and dosage schedule



Store at room temperature 20°-25°C (68°-77°F).
 EXPECTORANT. SUGAR & ALCOHOL FREE
 KEEP THIS AND ALL MEDICATION OUT OF
 THE REACH OF CHILDREN

17856-0117-05 Dosage: 100MG/5ML

GUAIFENESIN (SILTUSSIN SA) Qty: 72 CUPS



GTIN: 00117856011750

S/N: 01109701

Exp: 01/29/21

Lot: 011097

OTC

Packaged by: Unit Dose Solutions
 Morriceville, NC 27580

Distributed by: AtlanticBiologicals Corp,
 Miami Fl 33179

Rev.09/19

Call to Reorder: 800.509.7592

SILTUSSIN SA

guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0117(NDC:54838-117)
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

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
D&C yellow no. 10 (UNII: 35SW5USQ3G)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C red no. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
propylene glycol (UNII: 6DC9Q167V3)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium citrate (UNII: 1Q73Q2JULR)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0K00R)	

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:17856-0117-1	15 mL in 1 CUP; Type 0: Not a Combination Product	05/03/2016	10/16/2019
2	NDC:17856-0117-2	10 mL in 1 CUP; Type 0: Not a Combination Product	05/03/2016	10/16/2019
3	NDC:17856-0117-5	5 mL in 1 CUP; Type 0: Not a Combination Product	10/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/05/1998	

Labeler - Atlantic Biologicals Corps (047437707)

Registrant - Atlantic Biologicals Corps (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
Atlantic Biologicals Corps		047437707	RELABEL(17856-0117) , REPACK(17856-0117)