

**SILTUSSIN SA- guaifenesin liquid**  
**Proficient Rx LP**

*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 SA (Guaifenesin Liquid)**

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

Purpose: Expectorant

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

**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

**Stop use and ask a doctor** 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.

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
- repeat dose every 4 hours

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adults and children 12 years and over

2-4 teaspoonfuls (TSP)

**children under 12 years**

**DO NOT USE**

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**Other information**

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

Manufactured by:

Silarx Pharmaceuticals, Inc.  
 1033 Stoneleigh Ave  
 Carmel, NY 10512  
 USA

Repackaged by:  
 Proficient Rx LP  
 Thousand Oaks, CA 91320



NDC 63187-341-08

Lot #:00000  
 Exp. 00/00/00  
 SN# MASTER

**Siltussin SA (Guaifenesin Liquid) 100mg/ 5ml**

**237ml(8oz) Syrup**

Each 5ml (1tsp) contains: Guaifenesin 100mg

*Guaifenesin liquid as expectorant  
 See bottle label for dosage and storage instructions*

Product ID: RS034108

Mfr. By: Silarx Pharmaceuticals, Inc. 1033 Stoneleigh Ave Carmel, NY 10512 USA

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

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Relabeled By: Proficient Rx LP  
 Thousand Oaks, CA 91320

<b>SILTUSSIN SA</b>			
guaifenesin liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63187-341(NDC:54838-117)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)		Guaifenesin	100 mg in 5 mL
<b>Inactive Ingredients</b>			
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)			

<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>sodium benzoate</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>sorbitol</b> (UNII: 506T60A25R)	
<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:63187-341-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

### Marketing Information

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

**Labeler** - Proficient Rx LP (079196022)

### Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079502574	REPACK(63187-341) , RELABEL(63187-341)

Revised: 1/2019

Proficient Rx LP