SILTUSSIN SA- guaifenesin 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.

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

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

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

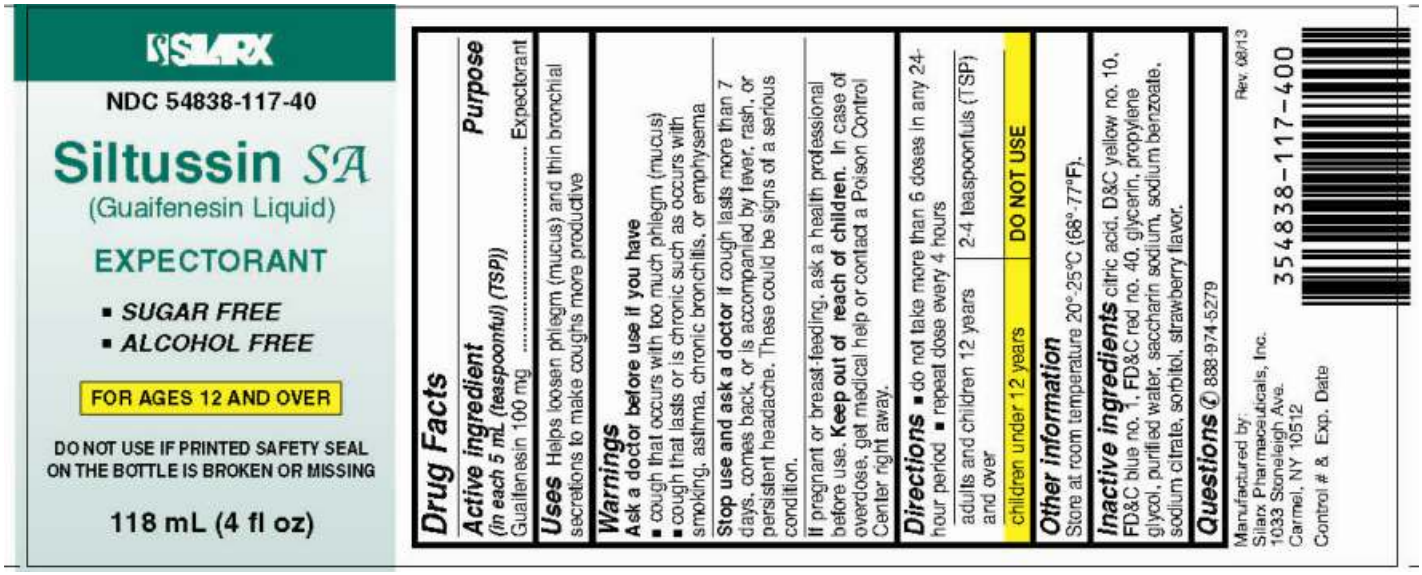
citric acid, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, strawberry flavor, glycerin, propylene glycol, saccharin sodium, sodium benzoate, sodium citrate, sorbitol, purified water.

Questions

888-974-5279

Manufactured by:

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



SILTUSSIN SA

guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	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 dihydrate (UNII: SB8ZUX40TY)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium citrate (UNII: 1Q73Q2JULR)	
sorbitol (UNII: 506T60A25R)	

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:54838-117-40	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:54838-117-70	237 mL in 1 BOTTLE, PLASTIC		
3	NDC:54838-117-80	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	10/05/1998	

Labeler - Silarx Pharmaceuticals, Inc (161630033)

Revised: 6/2014 Silarx Pharmaceuticals, Inc