

SILTUSSIN SA- guaifenesin liquid
Lannett Company, 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, glycerin, menthol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol, strawberry flavor.

Questions

1-844-834-0530

Manufactured by:

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



NDC 54838-117-40

Siltussin SA

(Guaifenesin Liquid)

EXPECTORANT

- SUGAR FREE
- ALCOHOL FREE

FOR AGES 12 AND OVER

DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING

118 mL (4 fl oz)

Drug Facts

Active ingredient (in each 5 mL teaspoonful) (USP) Guaifenesin 100 mg.....Expectorant

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Silarx Pharmaceuticals, Inc.
1033 Stoneleigh Ave., Carmel, NY 10512
10-1036 Rev. 03/18



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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)	
MENTHOL (UNII: L7T10EIP3A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	

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; Type 0: Not a Combination Product	10/05/1998	12/31/2024
2	NDC:54838-117-70	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/05/1998	09/30/2024
3	NDC:54838-117-80	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/05/1998	11/30/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/05/1998	12/31/2024

Labeler - Lannett Company, Inc. (002277481)

