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

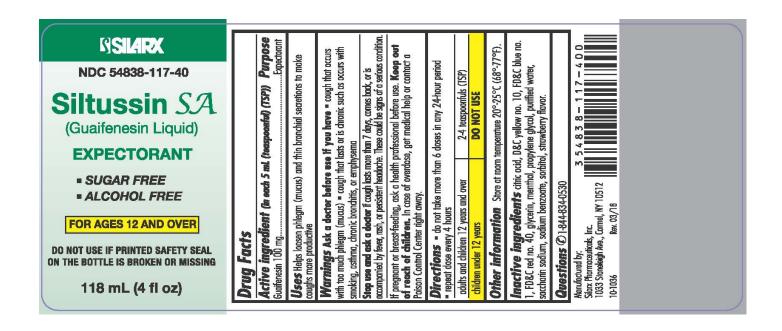
citric acid, D&C yellow no. 10, FD&C blue no. 1, FD&C red no. 40, glycerin, menthol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol, strawberry flavor.

Questions

1-844-834-0530

Manufactured by:

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



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 | |
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Revised: 6/2021 Lannett Company, Inc.