

SILTUSSIN SA- guaifenesin liquid
Preferred 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

1-844-834-0530

Manufactured by:

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

Relabeled By: Preferred Pharmaceuticals Inc.

<p>Siltussin SA (Sugar Free, Alcohol Free) Generic for Robitussin Each 5ml contains Guaifenesin, USP 100mg Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Silarx Pharmaceuticals, Inc. Prod#: Warning <small>Do not use if printed safety seal on the bottle is broken or missing. 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. For ages 12 and over. Store at room temperature 20°-25°C (68°-77°F). Guaifenesin Liquid, Expecto-rant.</small></p>	 <p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p>	<p>Siltussin SA (Sugar Free, Alcohol Free) Qty: Ins: Lot#: Bat#:</p> <p>Prod# (NDC): Siltussin SA (Sugar Free, Alcohol Free) Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Siltussin SA (Sugar Free, Alcohol Free) Qty: Insurance NDC: Lot#: Bat#:</p> <p>Siltussin SA (Sugar Free, Alcohol Free) Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>	<p>Log</p> <p>Chart</p> <p>Billing</p> <p>Patient</p>
<p>Directions English Take _____ teaspoonful(s) every _____ hours. Take as Directed</p>		<p>Instrucciones Español: Toma _____ cucharadita(s) cada _____ horas Tomelo como se indica</p>	

SILTUSSIN SA			
guaifenesin liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-9098(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, UNSPECIFIED FORM (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:68788-9098-1	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/05/1998	12/30/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/05/1998	12/30/2024

Labeler - Preferred Pharmaceuticals, Inc (791119022)

Registrant - Preferred Pharmaceuticals, Inc (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc		791119022	RELABEL(68788-9098)

Revised: 9/2023

Preferred Pharmaceuticals, Inc