SOFTSHEENCARSON MAGIC BUMP RESCUE SPOT TREATMENT- salicylic acid lotion L'Oreal USA Products 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.

Drug Facts

Active ingredient

Salicylic acid 2%

Purpose

Acne treatment

Uses

- for the treatment of acne
- clears up acne blemishes and allows skin to heal

Warnings

For external use only

Flammable until dry

Do not use near fire, flame or heat.

When using this product

skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer one to three times daily
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day

Inactive ingredients

water, alcohol denat., glycerin, propylene glycol, triethanolamine, acrylates/c10-30 alkyl acrylate crosspolymer, capryloyl salicylic acid, disodium EDTA, zinc gluconate, menthol, benzyl salicylate,

Questions or comments?

Call us Toll-Free in ther US: 1-800-442-4643

Monday - Friday 9 am - 5 pm EST



SOFTSHEENCARSON MAGIC BUMP RESCUE SPOT TREATMENT

salicylic acid lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-933	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
CAPRYLO YL SALICYLIC ACID (UNII: 5F7PJF6 AA4)		
ZINC GLUCONATE (UNII: U6 WSN5SQ1Z)		
MENTHOL (UNII: L7T10EIP3A)		
BENZYL SALICYLATE (UNII: WAO5MNK9TU)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		

l	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:49967-933- 01	1 in 1 CARTON	11/0 1/20 13		
	1	10 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	11/0 1/20 13		

Labeler - L'Oreal USA Products Inc (002136794)

Establishment				
Name	Address	ID/FEI	Business Operations	
Les Emballages Facoteck Inc.		245423439	manufacture(49967-933)	

Revised: 12/2019 L'Oreal USA Products Inc