

SR RENEW - dimethicone cream
International Brand Management, LLC

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

Dimethicone 5.0%

Skin Protectant

Uses

-temporarily protects and help relieve chapped or cracked skin

Warnings

For external use only

Do not use on -deep or puncture wounds -animal bites

-serious burns

When using this product -do not get into eyes

Stop use and ask a doctor if -condition worsens

-symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

-apply cream liberally as needed.

Other information

-protect from freezing avoid excessive heat

Inactive Ingredients Aloe Barbadensis Leaf (Aloe Vera Gel)

Juice, Aqua (Deionized Water), Cetyl Alcohol, DEA-Cetyl

Phosphate, Ethylhexylglycerin, Glyceryl Stearate, Glyceryl

Stearate SE, C13-14 Isoparaffin, Laureth-7, Octyl Palmitate,

PEG-100 Stearate, Phenoxyethanol, Polyacrylamide,

Polysorbate-20, Propylene Glycol, Stearic Acid, Tocopheryl

Acetate (Vitamin E).

NDC 69837-310-10

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FOR QUESTIONS OR COMMENTS: 800-992-1190
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Distributed By:
PIMD
8280 NW 27th Ave
Doral, FL 33122

Sure Result

SR Renew Dimethicone 5% Cream

Hypo-Allergenic

Rx Only

4 fl oz / 118 mL

SR RENEW

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69837-310
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69837-310-10	1 in 1 CARTON		
1		118 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2016	

Labeler - International Brand Management, LLC (079794940)

Establishment

Name	Address	ID/FEI	Business Operations
International Brand Management, LLC		079794940	manufacture(69837-310)

Revised: 2/2016

International Brand Management, LLC