

SPF RX - MINERAL SUNSCREEN SPF 30- zinc oxide, titanium dioxide cream
Cal Pharma 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.

ACTIVE INGREDIENTS

Zinc Oxide 5%

Titanium Dioxide 3%

Purpose

Sunscreen

USES

Helps prevent sunburn. If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer, early skin aging by the sun.

WARNINGS

For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash occurs.

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

DIRECTIONS

Apply liberally 15 minutes before sun exposure. Reapply:

- After 80 minutes of swimming or sweating
- At least every 2 hours. Immediately after towel drying.

Sun Protection Measures: Spending time in the sun increases your risk of skin cancer & early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months. Ask a doctor.

INACTIVE INGREDIENTS

Benzoic Acid, C12-15 Alkyl Benzoate, Caprylic/Capric Triglycerides, Cetyl PEG/PPG-10/1 Dimethicone, Dicaprylyl Ether, Ethylhexylglycerin, Glycereth-2 Cocoate, Glycerin, Isostearic Acid, Stearyl/Octyldodecyl Citrate Crosspolymer, Polyhydroxystearic Acid, Propanediol, Sodium Chloride, Sodium Hyaluronate, Tocopheryl Acetate (Vitamin E Acetate), Triethoxycaprylylsilane, Water.

OTHER INFORMATION

Protect this product from excessive heat and direct sun.

Drug Facts **SPF Rx**

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Distributed By:
Cal Pharma
www.cal-pharma.com
MADE IN THE USA

Please Recycle

Your Prescription for
Sunscreen Naturally

Broad Spectrum Protection

Mineral Sunscreen

Zinc Oxide & Titanium Dioxide

SPF 30

Water Resistant
(80 minutes)

4 fl oz / 120 ml

SPF RX - MINERAL SUNSCREEN SPF 30

zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55628-8569
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 g in 100 g	
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	BENZOIC ACID (UNII: 8SKN0B0MIM)			
	ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
	CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)			
	DICAPRYLYL ETHER (UNII: 77JZM5516Z)			
	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
	GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	ISOSTEARIC ACID (UNII: X33R8U0062)			
	OCTYLDODECYL STEARATE (UNII: K6F16QGO28)			
	POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
	PROPANEDIOL (UNII: 5965N8W85T)			
	SODIUM CHLORIDE (UNII: 451W47IQ8X)			
	HYALURONATE SODIUM (UNII: YSE9PPT4TH)			
	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
	TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)			
	WATER (UNII: 059QF0K00R)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55628-8569-4	120 g in 1 TUBE; Type 0: Not a Combination Product	07/30/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	07/30/2017		

Labeler - Cal Pharma LLC (078721283)

Registrant - Cal Pharma LLC (078721283)

Establishment

Name	Address	ID/FEI	Business Operations
Health Specialty		794053863	manufacture(55628-8569)