SPF RX - MINERAL SUNSCREEN SPF 40- 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 20%

Titanium Dioxide 1%

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

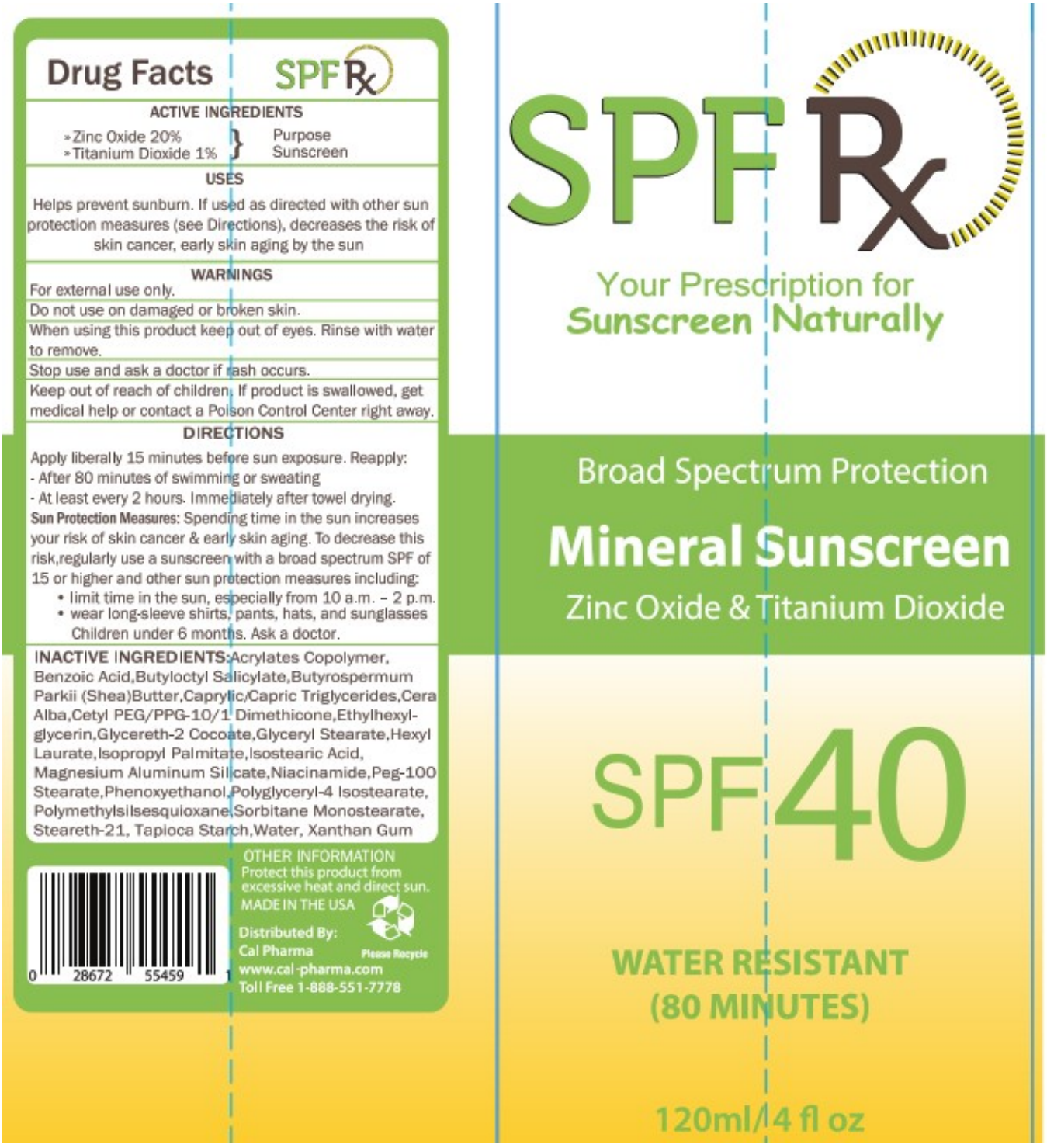
• Children under 6 months. Ask a doctor.

INACTIVE INGREDIENTS

Acrylates Copolymer, Benzoic Acid, Butyloctyl Salicylate, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglycerides, Cera Alba (Beeswax), Cetyl PEG/PPG-10/1 Dimethicone, Ethylhexylglycerin, Glycereth-2 Cocoate, Glyceryl Stearate, Hexyl Laurate, Isopropyl Palmitate, Isostearic Acid, Magnesium Aluminum Silicate, Niacinamide, PEG-100 Stearate, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Sorbitan Monostearate, Steareth-21, Tapioca Starch, Water, Xanthan Gum

OTHER INFORMATION

Protect this product from excessive heat and direct sun.



SPF RX - MINERAL SUNSCREEN SPF 40

zinc oxide, titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55628-9228
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SHEA BUTTER (UNII: K49155WL9Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WHITE WAX (UNII: 7G1J5DA97F)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERETH-2 COCOATE (UNII: JWM00VS7HC)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARETH-21 (UNII: 53J3F32P58)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55628-9228-4	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(55628-9228)

Revised: 7/2017

Cal Pharma LLC