SANTO REMEDIOS PIEL ETERNA RADIANCE SUNSCREEN PRIMER SPF-42titanium dioxide, zinc oxide lotion SANTO REMEDIO LLC

SANTO REMEDIO'S Piel Eterna Radiance Sunscreen Primer SPF-42

Drug Facts

Active ingredients

Titanium Dioxide 6% Zinc Oxide 8%

Purpose

Sunscreen

Uses:

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Retains SPF after 80 minutes of swimming or sweating.
- If used as as directed with other sun protection measures (see directions), decreases the risk of cancer and early skin aging caused 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 doctor if

Rash occurs.

Keep out of reach of children.

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

If pregnant or breastfeeding,

Ask a health professional before use.

Directions:

• Apply liberally 15 minutes before sun exposure and as needed.

- Children under 6 months of age: ask a doctor.
- Reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- Sun Protection Measures.
- Limit time in the sun, especially from 10 a.m. 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

Other information.

• Protect the product in this container from excessive heat and direct sun.

Inactive Ingredients:

Bis-Vinyl Dimethicone/ Dimethicone, Copolymer, Camellia Sinensis (Green Tea) Extract, Caprylic/ Capric Triglyceride, Cetyl, PEG/PPG-10/1 Dimethicone, Cocos Nucifera (Coconut) Oil, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone, Dimethiconol, Helianthus Annus (Sunflower) Oil, Iron Oxides (Black, Red, White, Yellow), Rubus Idaeus (Rasperry) Extract, Silica, Tetrahexyldecyl Ascorbate (Vitamin C), Tocopheryl Acetate (Vitamin E), Tridecyl Salicylate.

Questions?
(855) REMEDIO

Package Labeling:



SANTO REMEDIOS PIEL ETERNA RADIANCE SUNSCREEN PRIMER SPF-42

titanium dioxide, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81352-321
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
COCONUT OIL (UNII: Q9L0O73W7L)		
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)		
CYCLOMETHICONE 4 (UNII: CZ227117JE)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
RASPBERRY (UNII: 4N14V5R27W)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81352-321- 00	50 mL in 1 TUBE; Type 0: Not a Combination Product	03/21/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/21/2022	

Labeler - SANTO REMEDIO LLC (117456185)

Revised: 11/2023 SANTO REMEDIO LLC