

VACATION MINERAL BROAD SPECTRUM SPF 30 SUNSCREEN- zinc oxide lotion
Vacation 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.

VACATION® MINERAL BROAD SPECTRUM SPF 30 SUNSCREEN

Drug Facts

Active ingredients

Zinc Oxide 20%

Purpose

Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin 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 a doctor if rash occurs

Keep out of reach of children. In case of ingestion, 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
 - immediately after towel drying
 - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the 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 of age: ask a physician.

Inactive ingredients

Allantoin, Aloe Barbadensis (Aloe Vera) Leaf Extract, Butyrospermum Parkii (Shea) Butter, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride, Capryloyl Glycerin/Sebacic Acid Copolymer, Caprylyl Caprylate/Caprates, Caprylyl Glyceryl Ether, Cucumis Sativus (Cucumber) Fruit Extract, Dicaprylyl Carbonate, Diheptyl Succinate, Galactoarabinan, Glycerin, Helianthus Annuus (Sunflower) Extract, Magnesium Sulfate, Methyl Dihydroabietate, Niacinamide (Vitamin B3), Oryza Sativa (Rice) Bran Extract, Polyglyceryl-2 Oleate, Polyglyceryl-2 Stearate, Polyhydroxystearic Acid, Propanediol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol (Vitamin E), Triethoxycaprylylsilane, Water

Other information

- Protect this product from excessive heat and direct sun

Distributed by

Vacation Inc.

936 SW 1st Ave #888

Miami, FL 33130

PRINCIPAL DISPLAY PANEL - 100 ML Tube Label

Vacation®

Mineral Lotion

BROAD SPECTRUM SPF 30 SUNSCREEN

By the "Legendary" Vacation® of Miami—
"Luxury-Grade" Non-Nano Zinc Formula
Sunscreen for "Long Days by the Pool"
Water-Resistant (80 Minutes)
"Leisure-Enhancing"

SPF 30

3.4 FL OZ / 100 ML

Vacation®

Center
Front Panel



Mineral Lotion

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Center
Art Work

True Connoisseurs of Leisure Insist on the “World-Famous” Vacation®

- ✓ OXYBENZONE FREE
- ✓ PARABEN FREE
- ✓ CRUELTY FREE
- ✓ NON-NANO ZINC FORMULA
- ✓ OCTINOXATE FREE
- ✓ FRAGRANCE FREE
- ✓ VEGAN
- ✓ REEF FRIENDLY

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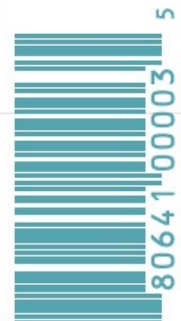
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936 SW 1st Ave #888
Miami, FL 33130



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Enhance Leisure



VACATION MINERAL BROAD SPECTRUM SPF 30 SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80641-002
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 mL

Inactive Ingredients

Ingredient Name	Strength
Allantoin (UNII: 344S277G0Z)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Shea Butter (UNII: K49155VL9Y)	
Caprylhydroxamic Acid (UNII: UPY805K99W)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
Caprylyl Caprylate/Caprates (UNII: 22MCG4RSMR)	
Caprylyl Glyceryl Ether (UNII: MI97BW74XZ)	
Cucumber (UNII: YY7C30VXJT)	
Dicaprylyl Carbonate (UNII: 609A3V1SUA)	
Diheptyl Succinate (UNII: 057N7SS26Y)	
Galactoarabinan (UNII: SL4SX1O487)	
Glycerin (UNII: PDC6A3C0OX)	
Helianthus Annuus Flowering Top (UNII: BKJ0J3D1BP)	
Magnesium Sulfate, Unspecified Form (UNII: DE08037SAB)	
Methyl Dihydroabietate (UNII: 7666FJ0J9F)	
NIACIN (UNII: 2679MF687A)	
Rice Bran (UNII: R60QEP13IC)	
Polyglyceryl-2 Oleate (UNII: 5759J47SAM)	
Polyglyceryl-2 Stearate (UNII: 253MC0P0YV)	
Propanediol (UNII: 5965N8W85T)	
Rosemary (UNII: IJ67X351P9)	
.Alpha.-Tocopherol (UNII: H4N855PNZ1)	
Triethoxycaprylylsilane (UNII: LDC331P08E)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80641-002-01	100 mL in 1 TUBE; Type 0: Not a Combination Product	05/19/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/19/2021	

Labeler - Vacation Inc. (117644631)