VANICREAM SUNSCREEN SPORT BROAD SPECTRUM SPF 35- zinc oxide cream Pharmaceutical Specialties, Inc.

VANICREAM Sunscreen Sport Broad Spectrum SPF35

Drug Facts

Active ingredient

Zinc oxide 12%

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

Directions

- shake well before use
- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months of age: Ask a doctor.
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value 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-sleeved shirts, pants, hats and sunglasses

Other information

protect this product from excessive heat and direct sun

Inactive ingredients allantoin, butyloctyl salicylate, C12-15 alkyl benzoate, caprylyl glycol, glyceryl behenate, glyceryl dibehenate, glyceryl stearate, lecithin, neopentyl glycol diheptanoate, 1,2-hexanediol, polyester-7, polyglyceryl-3 polyricinoleate, propanediol,

silica, sodium chloride, squalane, tribehenin, tridecyl salicylate, water

Questions or Comments?

1-800-325-8232

www.vanicream.com

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Dist. by

PHARMACEUTICAL SPECIALTIES, INC.

ROCHESTER, MN 55901 Made in U.S.A.

NDC 45334-331-03

DERMATOLOGIST TESTED

New Formula

VANICREAM™ Sunscreen Sport

BROAD SPECTRUM SPF 35

MINERAL SUNSCREEN

WATER RESISTANT (80 MINUTES)

NON-COMEDOGENIC

Free of dyes, fragrance, masking fragrance, lanolin, parabens & formaldehyde releasers

Gluten-free

for Sensitive Skin

Net Wt 3 oz (85 g)



VANICREAM SUNSCREEN SPORT BROAD SPECTRUM SPF 35

zinc oxide cream

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:45334-331 |
|-------------------------|----------------|--------------------|---------------|
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|--------------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 12 g in 100 g |

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| GLYCERYL 1,3-DIBEHENATE (UNII: 84T2X52XS0) | | |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4) | | |
| 1,2-HEXANEDIOL (UNII: TR046Y3K1G) | | |
| POLYESTER-7 (UNII: 0841698D2F) | | |
| SQUALANE (UNII: GW89575KF9) | | |
| NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X) | | |
| PROPANEDIOL (UNII: 5965N8W85T) | | |
| TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1) | | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | | |
| TRIBEHENIN (UNII: 80C9U7TQZ0) | | |
| WATER (UNII: 059QF0KO0R) | | |
| POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W) | | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | | |
| ALLANTOIN (UNII: 344S277G0Z) | | |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | | |
| GLYCERYL MONOBEHENATE (UNII: A626UU0W2A) | | |

| P | Packaging | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:45334-331- 03 | 1 in 1 CARTON | 04/27/2021 | 11/30/2024 | | |
| 1 | | 85 g 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 Drug | M020 | 04/27/2021 | 11/30/2024 | |
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Revised: 11/2023 Pharmaceutical Specialties, Inc.