VANICREAM SUNSCREEN BROAD SPECTRUM SPF 50- zinc oxide cream Pharmaceutical Specialties, Inc.

VANICREAM Sunscreen BROAD SPECTRUM SPF 50+

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:
 - o 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, dimethiconol/propylsilsesquioxane/silicate crosspolymer, glyceryl behenate, glyceryl dibehenate, glyceryl stearate, isodecyl salicylate, isopropyl isostearate, lecithin, neopentyl glycol diheptanoate, 1,2-hexanediol, polyester-7, polyglyceryl-3 polyricinoleate,

propanediol, silica silylate, 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 USA

NDC 45334-332-03

DERMATOLOGIST TESTED

New Formula

VANICREAM™ Sunscreen

BROAD SPECTRUM SPF 50+

MINERAL SUNSCREEN

WATER RESISTANT (80 MINUTES)

NON-COMEDOGENIC

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

Gluten-Free

for Sensitive Skin

Net Wt 3 oz (85 g)



VANICREAM SUNSCREEN BROAD SPECTRUM SPF 50

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45334-332
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T)	
ALLANTOIN (UNII: 344S277G0Z)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONOL/PROPYLSILSESQUIOXANE/SILICATE CROSSPOLYMER (450000000 MW) (UNII: 9KB5R958PB)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
GLYCERYL 1,3-DIBEHENATE (UNII: 84T2X52XS0)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
ISODECYL SALICYLATE (UNII: S7097PFP4C)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
WATER (UNII: 059QF0KO0R)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
POLYESTER-7 (UNII: 0841698D2F)	
SQUALANE (UNII: GW89575KF9)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
PROPANEDIOL (UNII: 5965N8W85T)	
SILICA, TRIMETHYLSILYL CAPPED (UNII: VU10KU4B9S)	
TRIBEHENIN (UNII: 80C9U7TQZ0)	

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:45334-332- 03	1 in 1 CARTON	04/05/2021		
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	04/05/2021		

Labeler - Pharmaceutical Specialties, Inc. (076499557)

Revised: 10/2023 Pharmaceutical Specialties, Inc.