

NISEKO SUNSCREEN SPF 25- avobenzone, octinoxate, and octisalate cream
Medimetriks Pharmaceuticals, 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.

Niseko™ Sunscreen SPF 25

Drug Facts

Active Ingredient

Avobenzone 3.0%

Octinoxate 7.5%

Octisalate 5.0%

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

Directions

- apply liberally 15 minutes before sun exposure
- apply to all skin exposed to the sun
- reapply:
 - at least every 2 hours
 - use water-resistant sunscreen if swimming or sweating
- **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 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

Purified Water, Cyclomethicone, C12-15 Alkyl Lactate, Butyloctyl Salicylate, Glyceryl Stearate SE, Isododecane, Glycerin, Cetearyl Alcohol, Butylene/Ethylene/Propylene Copolymer, Polyacrylamide, Cetyl Alcohol, Dicapryl Phosphate, Ceteth-10 Phosphate, Cholesterol, Tocopheryl Acetate, Edetate Disodium, Methylparaben, Phenoxyethanol, Xanthan Gum, Camellia Sinensis Leaf (Green Tea) Extract, Camellia Sinensis Leaf (White Tea) Extract, C13-C14 Isoparaffin, Laureth-7.

Other information

- protect product from excessive heat and direct sun

Questions or comments?

call 1-973-882-7512

Mfd. by: IGI Laboratories, Inc., Buena, NJ 08310

PRINCIPAL DISPLAY PANEL - 85 g Tube Carton

niseko®

SUNSCREEN

Broad Spectrum

SPF 25

UVA/UVB Protection

Formulated with

Green & White Tea • Vitamin E

Dermatologist-tested

Non-comedogenic

Net Wt. 3 oz (85 g)

MEDIMETRIKS

PHARMACEUTICALS, INC.

niseko®

SUNSCREEN
Broad Spectrum
SPF 25

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SUNSCREEN
Broad Spectrum
SPF 25

Niseko® Sunscreen is a unique, Dermatologist-tested sunscreen designed for patients with sensitive skin. The gentle formula combines the antioxidant benefits of Green Tea and White Tea with Vitamin E to help support overall skin health. As a broad spectrum sunscreen, when used as directed and along with other sun protection measures, Niseko® Sunscreen may also reduce the risk of skin cancer and early skin aging.

Net Wt. 3 oz (85g)

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PHARMACEUTICALS, INC.

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Questions or comments? call 1-873-882-7512

Mfd. for: Medimetriks Pharmaceuticals, Inc., 383 Route 46 West, Fairfield, NJ 07004-2402 USA www.medimetriks.com

Mfd. by: Telligent Pharma, Inc., Buena, NJ 08310 Made in USA IC125-R1

C100754 Sunscreen 3oz



NISEKO SUNSCREEN SPF 25

avobenzone, octinoxate, and octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43538-290
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	75 mg in 1 g
Octisalate (UNII: 4X49 Y0596 W) (Octisalate - UNII:4X49 Y0596 W)	Octisalate	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
C12-15 Alkyl lactate (UNII: GC844VRD7E)	
butyloctyl salicylate (UNII: 2EH13UN8D3)	
Glyceryl Stearate SE (UNII: FCZ5MH785I)	
isododecane (UNII: A8289P68Y2)	
glycerin (UNII: PDC6A3C0OX)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetyl alcohol (UNII: 936JST6JCN)	
dihexadecyl phosphate (UNII: 2V6E5WN99N)	
ceteth-10 phosphate (UNII: 4E05O5N49G)	
cholesterol (UNII: 97C5T2UQ7J)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
edetate disodium (UNII: 7FLD91C86K)	
methylparaben (UNII: A28C7H9T)	
phenoxyethanol (UNII: HIE492ZZ3T)	
xanthan gum (UNII: TTV12P4NEE)	
green tea leaf (UNII: W2ZU1RY8B0)	
C13-14 isoparaffin (UNII: E4F12ROE70)	
Laureth-7 (UNII: Z95S6G8201)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43538-290-99	6 in 1 CARTON	11/15/2013	
1		3 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:43538-290-03	1 in 1 CARTON	11/15/2013	
2		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 FINAL	part352	11/15/2013	

Labeler - Medimetriks Pharmaceuticals, Inc. (019903816)

Establishment

Name	Address	ID/FEI	Business Operations
Teligent Inc		011036910	MANUFACTURE(43538-290)

Revised: 12/2018

Medimetriks Pharmaceuticals, Inc.