SUN DEFENSE UVSCREEN SPF 48 - ensulizole homosalate octinoxate octocrylene zinc oxide cream
Kamins Dermatologics 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.

SUN DEFENSE UVscreen SPF48 CONSUMER LABELING

Active ingredients:

Ensulizole 3%

Homosalate 10%

Octinoxate 7.5%

Octocrylene 7%

Zinc oxide 8%

Purpose: Sunscreen

Keep out of reach of children.

A hydrating, broad spectrum UVA/UVB sunscreen, which provides protection against sunburn. Combines our moisturizing Bio-Maple^{TM} compound with a mixture of sunscreens that protect skin by scattering, reflecting and absorbing harmful sun rays. Fragrance, color and oil-free, ideal for those with sensitive skin.

Uses

■ Helps prevent sunburn.

■ Higher SPF gives more sunburn protection.

■ Provides high protection against sunburn.

Warnings

For external use only.

Avoid contact with eyes when using this product. If contact occurs, rinse abundantly with water to remove.

Discontinue use in case of excessive skin irritation or if condition does not improve. If irritation persists, consult a health care practitioner.

If swallowed, seek medical assistance or contact a Poison Control Center immediately.

Other information
Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Store at room temperature 15-30°C (59-86°F).

Directions

■ Apply liberally and evenly to face and exposed areas 15-30 minutes before sun exposure.

■ Reapply every two hours or as needed.

■ Reapply after swimming, towel drying, washing or perspiring heavily.

■ Consult a doctor before using on children under six months of age.

Inactive ingredients: water, cyclopentasiloxane, dimethiconol, acer saccharum (maple isolate), glycerin, cyclohexasiloxane, cetearyl alcohol, steareth-100, polyacrylamide, C13-14 isoparaffin, laureth-7, steareth-2, dimethicone, VP/eicosene copolymer, lactic acid, sodium hydroxide, dimethoxydiphenylsilane/triethoxycaprylylsilane crosspolymer, tocopheryl acetate, xanthan gum, phenoxyethanol, chlorphenesin.

SUN DEFENSE UVscreen SPF 48

120 mL / 4 fl. oz

DIN 02280329

image/jpg

B. KAMINS
laboratories

Sun Defense
UV screen SPF 48
Écran solaire UV

SUN DEFENSE UVSCREEN SPF 48

ensulizole homosalate octinoxate octocrylene zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63550-852
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	70 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ACER SACCHARUM SAP (UNII: 75UOH57984)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARETH-100 (UNII: 4OH5W9UM87)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
STEARETH-2 (UNII: V56DFE46J5)	
LACTIC ACID (UNII: 33X04XA5AT)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63550-852-10	120 mL in 1 BOX		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/02/2011	

Labeler - Kamins Dermatologics Inc. (254050784)

Registrant - Kamins Dermatologics Inc. (254050784)

Establishment

Name	Address	ID/FEI	Business Operations
Kamins Dermatologics Inc.		254050784	manufacture, pack, label