

SOLVADERM - DERMAXSOL- octinoxate and zinc oxide cream
Cosmetic Solutions LLC

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.

Solvaderm™ - Dermaxsol

DRUG FACTS:

ACTIVE INGREDIENTS

Octyl Methoxycinnamate 7.5%, Zinc Oxide 7.0%.

Purpose

Sunscreen

USES

Helps prevent sunburn.

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 to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure. *Reapply at least every 2 hours. *Use a water-resistant sunscreen if swimming or sweating. *For 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.

INACTIVE INGREDIENTS

Water (Aqua), Stearyl Alcohol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Glyceryl Dilaurate, Cetearyl Alcohol, Beeswax, Dimethicone, Cyclomethicone, Diisopropyl Adipate, Hexylene Glycol, PEG-40 Stearate, C12-15 Alkyl Benzoate, Aluminum Starch Octenylsuccinate, PEG-20, Carnuba Wax, Dimethicone Copolyol, VP/Eicosene Copolymer, Sorbitan Tristearate, Stearoxytrimethylsilane, Steareth-100, Laureth-7, C13-14 Isoparaffin, Phenoxyethanol, Ethylhexylglycerin, Polyacrylamide.

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sun.

Distributed By:

Solvaderm Skincare
Spring Valley, NY 10977

PRINCIPAL DISPLAY PANEL - 50 g Bottle Label

SOLVADERM™
REDEFINING SKIN SCIENCE
DERMAXSOL
Dermal defense moisturizer
SPF 30 - Sunscreen Broad Spectrum
Net Wt.
1.75oz (50g)



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SOLVADERM - DERMASOL			
octinoxate and zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66 163-6402
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)		Octinoxate	75 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)		Zinc Oxide	70 mg in 1 g
Inactive Ingredients			

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
Glycerin (UNII: PDC6A3C0OX)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
PEG-100 Stearate (UNII: YD01N1999R)	
Glyceryl Dilaurate (UNII: MFL3ZIE8SK)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Dimethicone (UNII: 92RU3N3Y1O)	
Cyclomethicone (UNII: NMQ347994Z)	
Diisopropyl Adipate (UNII: P7E6 YFV72X)	
Hexylene Glycol (UNII: KEH0A3F75J)	
PEG-40 Stearate (UNII: ECU18C66Q7)	
Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)	
Aluminum Starch Octenylsuccinate (UNII: I9PJ0O6294)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
Carnauba Wax (UNII: R12CBM0EIZ)	
PEG/PPG-18/18 Dimethicone (UNII: 9H0AO7T794)	
Sorbitan Tristearate (UNII: 6LUM696811)	
Stearoxytrimethylsilane (UNII: 9862TW94B2)	
Stearth-100 (UNII: 4OH5W9UM87)	
Laureth-7 (UNII: Z95S6G8201)	
C13-14 Isoparaffin (UNII: E4F12ROE70)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-6402-1	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2019	

Labeler - Cosmetic Solutions LLC (807907928)