

THERADERMSPF 43 SPF 43- zinc oxide, octinoxate, octisalate emulsion
Therapon Skin Health, LP

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.

Theraderm

Active Ingredients

Zinc Oxide 7.50%Sunscreen
Octinoxate 7.50%Sunscreen
Octisalate 2.50%Sunscreen

Uses

Helps prevent sunburn and photo damage caused by UVA/UVB exposure.

Warnings

- For External use only.
- When using, avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- Stop use and contact a doctor if irritation or rash develops.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- Apply generously 15 minutes before sun exposure.
- Reapply to dry skin as needed.
- May be applied before make-up

Best used within 12 months of opening.

Inactive Ingredients

Purified water, Isopropyl palmitate, Octyl stearate, Ethyl hexyl isononanoate, Cyclopentasiloxane, Cetearyl glucoside, Dimethicone, Glycereth-26, Sodium Hyaluronate, Panthenol, Allantoin, Oleth-3 phosphate, Hydroxyethyl Acrylate/Sodium acryloyl dimethyl taurate copolymer, Polyisobutene, PEG-7 trimethylolpropane coconut ether, Polyether-1, Phenoxyethanol, Butylene glycol, Iodopropynyl butylcarbamate, Tocopheryl acetate, Triethoxycaprylylsilane.

Label for Tube and Box

Theraderm Tube Label

theraderm®

clinical skin care

Platinum Protection
Facial Sunscreen

SPF 43

90ml | 3 fl oz

Drug Facts

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Paraben Free • Oil Free
Fragrance Free • Non-Comedogenic

THERAPON
SKIN HEALTH®

1.800.443.7549
www.therapon.com

dist. by Therapon Skin Health
Springdale, AR 72764
Made in the USA



Theraderm Box Label

theraderm[®]

This broad-spectrum sunscreen provides the highest effective range (SPF 43) of UVA/UVB sun protection. The micronized zinc oxide and octinoxate shield the skin from the sun's damaging rays without clogging pores or producing a white sheen.

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Oil Free
Fragrance Free
Non-Comedogenic

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clinical skin care
Platinum Protection
Facial Sunscreen

SPF 43

30ml | 3.1 oz

THERAPON
SKIN HEALTH[®]

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THERADERMSPF 43 SPF 43

zinc oxide, octinoxate, octisalate emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66428-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	7.5 mL in 100 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 mL in 100 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	2.5 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Octyl Stearate (UNII: 772Y4UFC8B)	
Ethylhexyl Isononanoate (UNII: I6KB4GE3K4)	
Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Cetearyl Glucoside (UNII: 09FUA47KNA)	
Dimethicone (UNII: 92RU3N3Y1O)	
Glycereth-26 (UNII: NNE56F2N14)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Panthenol (UNII: WV9CM0O67Z)	
Allantoin (UNII: 344S277G0Z)	
Oleth-3 Phosphate (UNII: 8Q0Z18J1VL)	
2-Hydroxyethyl Acrylate (UNII: 25GT92NY0C)	
Polyisobutylene (1300 MW) (UNII: 241BN7J12Y)	
Coconut Alcohol (UNII: 13F4MW8Y9K)	
Polyester-7 (UNII: 0841698D2F)	
Ethylene Oxide (UNII: JJH7GNN18P)	
Polyethylene Glycol 350 (UNII: ZBR3T82M2V)	
Polyisobutylene (1300 MW) (UNII: 241BN7J12Y)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Iodopropynyl Butylcarbamate (UNII: 603P14DHEB)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
Triethoxycaprylsilane (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66428-002-02	1 in 1 BOX		

1	90 mL in 1 TUBE		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/20/2012	

Labeler - Therapon Skin Health, LP (792518995)

Establishment			
Name	Address	ID/FEI	Business Operations
Swiss American Products, Inc.		611921669	manufacture

Revised: 1/2012

Therapon Skin Health, LP