

**ESSENTIAL SHEER SPF 50- zinc oxide titanium dioxide lotion**  
**Topiderm, Inc.**

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**Essential Sheer**  
**SPF 50**

**Drug Facts**

**Active ingredients**

Zinc Oxide 14.5%

Octinoxate 7.5%

**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.**

**When using this product** keep out of eyes, rinse with water to remove.

**Stop use if** signs of irritation or rash appear. If irritation or rash persists consult a doctor.

**Keep out of reach of children.**

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

**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 sunscreen measures including:

- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses

**Directions**

- Apply liberally to face and neck and spread evenly 15 minutes before sun exposure
- Re-apply after swimming, excessive perspiring, or anytime after towel drying
- Use a water resistant sunscreen if swimming or sweating

- Use on children under 6 months of age: consult a doctor.

### **Inactive ingredients**

Purified Water, Niacinamide, Oleth-3 Phosphate, Neopentyl Glycol Diheptanoate, Polyisobutene, Octyldodecyl, Neopentanoate, Butylene Glycol, Tocopheryl Acetate, Sodium Hyaluronate, Caffeine, Panthenol, Dimethicone, Sucrose, Lactic Acid, Glycerin, Ethylhexyl Stearate, Triethoxycaprylylsilan, Xanthan Gum, Lauryl PEG Polydimethylsiloxylethyl Dimethicone, PEG-7 Trimethylolpropane Coconut Ether, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Phenoxyethanol, Disodium EDTA.

### **PRINCIPAL DISPLAY PANEL - 63 g Bottle Label**

COMPLIMENTS OF  
TOPIX  
PHARMACEUTICALS, INC

DAILY

Sheer Lightweight  
Brightening  
Sunscreen SPF 50

Broad Spectrum  
SPF 50 Sunscreen

FOR PATIENTS WITH ACNE,  
ROSACEA PRONE AND  
HYPERPIGMENTED SKIN

Net wt. 2.22 oz. (63 g)

Available  
Custom Branded  
800.445.2595  
c.service@topixpharm.com

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### Drug Facts (continued)

#### Warnings (continued)

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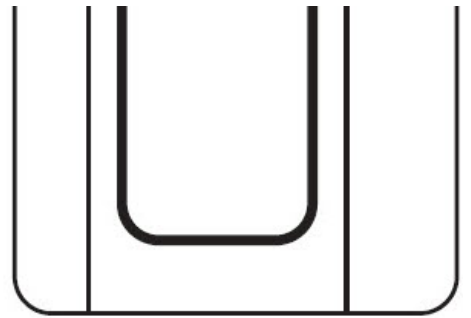
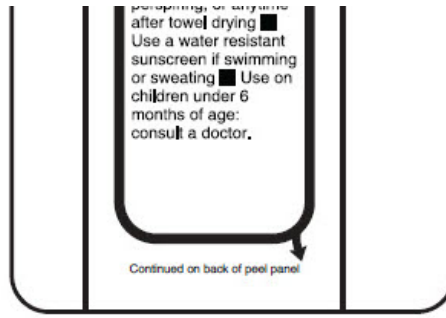
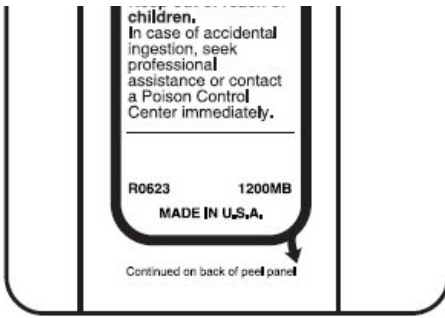
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## ESSENTIAL SHEER SPF 50

zinc oxide titanium dioxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51326-200
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	145 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	75 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>OLETH-3 PHOSPHATE</b> (UNII: 8Q0Z18J1VL)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>HYDROGENATED POLYISOBUTENE (1300 MW)</b> (UNII: 7D1YQ9Y5EZ)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>PANTHENOL</b> (UNII: WV9CM0067Z)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>PEG-7 TRIMETHYLOLPROPANE COCONUT ETHER</b> (UNII: MVJ3AD73GG)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S</b>	

AT 1.5%) (UNII: 86FQE96TZ4)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-200-01	63 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M020	07/29/2019	

**Labeler** - Topiderm, Inc. (049121643)

**Registrant** - Topiderm, Inc. (049121643)

### Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-200)

Revised: 7/2024

Topiderm, Inc.