

REPLENIX SHEER SPF 50- zinc oxide titanium dioxide cream
Topiderm, Inc.

Replenix® Sheer
SPF 50

Drug Facts

Active ingredient	Purpose
Zinc Oxide 16.5%	Sunscreen
Titanium Dioxide 2.3%	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 10a.m.-2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses

Directions

- Apply liberally and spread evenly by hand 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

Acrylates Crosspolymer-4, Ascorbic Acid, Biotin, Butyrospermum Parkii Butter, Camellia

Sinensis Leaf (Green Tea) Polyphenols, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Ceteth-10 Phosphate, Cyclomethicone, Dicapryl Phosphate, Dimethicone, Disodium EDTA, Hexyl Laurate, Isododecane, Lauryl PEG/PPG-18/18 Methicone, Lecithin, PEG-10 Dimethicone, Phenoxyethanol, Phyllanthus Emblica Fruit Extract, Polyhydroxystearic Acid, Polymethylsilsesquioxane, Polysilicone-11, Potassium Cetyl Phosphate, Potassium Hydroxide, Purified Water, Resveratrol, Stearic Acid, Ubiquinone (Coenzyme Q-10), Retinyl Palmitate, Xanthan Gum.

PRINCIPAL DISPLAY PANEL - 60 g Bottle Label

REPLENIX®

SHEER PHYSICAL

SUNSCREEN

SPF

50+

CREAM

UVA UVB

BROAD SPECTRUM SPF 50+

- Zinc Oxide 13.75%
- Green Tea Polyphenols
- Resveratrol
- Vitamin C
- Emblica
- CoQ10

Net 2 fl. oz. (60 ml)

Topix Pharmaceuticals, Inc.

N. Amityville, NY 11701

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Drug Facts (continued)

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Made in U.S.A.

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Phosphate, Dimethicone, Disodium EDTA, Hexyl Laurate, Isododecane, Lauryl PEG/PPG-18/18 Methicone, Lecithin, PEG-10 Dimethicone, Phenoxyethanol, Phyllanthus Emblica Fruit Extract, Polyhydroxystearic Acid, Polymethylsilsesquioxane, Polysilicone-11, Potassium Cetyl Phosphate, Potassium Hydroxide, Purified Water, Resveratrol, Stearic Acid, Ubiquinone (Coenzyme Q-10), Retinyl Palmitate, Xanthan Gum.

REPLENIX SHEER SPF 50

zinc oxide titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-858
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	165 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	23 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ACRYLATES CROSSPOLYMER-4 (UNII: GEV2EL4D9G)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BIOTIN (UNII: 6S06U10H04)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ISODODECANE (UNII: A8289P68Y2)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
PEG-10 DIMETHICONE (200 CST) (UNII: 287GF3Y3WC)	
PHENOXYETHANOL (UNII: HIE492Z33T)	
PHYLLANTHUS EMBLICA FRUIT (UNII: YLX4CW2576)	

POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
RESVERATROL (UNII: Q369O8926L)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
UBIDECARENONE (UNII: EJ27X76M46)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-858-01	60 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M020	07/23/2021	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-858)

Revised: 7/2024

Topiderm, Inc.