

MINERAL REPAIR SPF 45- zinc oxide lotion
Topiderm, Inc.

Mineral Repair SPF 45

Drug Facts

Active ingredient

Zinc Oxide 15%

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.

Directions

Apply liberally 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.
- **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

Inactive ingredients

Allantoin, Bromelain, C12-15 Alkyl Benzoate, C30-45 Alkyl Methicone, C30-45 Olefin,

Camellia Sinensis (Green Tea) Polyphenols, Dimethicone, Glyceryl Behenate, HDI/Trimethylol Hexyllactone Crosspolymer, Isodecyl Neopentanoate, Isononyl Isononanoate, Isostearic Acid, Papain, Phenoxyethanol, Phenyl Trimethicone, Polyhydroxystearic Acid, Silica, Tocopherol, Trimethylsiloxysilicate.

PRINCIPAL DISPLAY PANEL - 30 g Bottle Label

COMPLIMENTS OF

TOPIX
PHARMACEUTICALS, INC

Sheer Mineral
Repair SPF 45

Broad Spectrum SPF 45
UVA/UVB Sunscreen
Water Resistant (80 min)

Net wt. 1 oz. (30 g)

Available
Custom Branded
800.445.2595
c.service@topixpharm.com

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R0620

Made in U.S.A.

1245MB

MINERAL REPAIR SPF 45

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-245
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	150 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	
BROMELAINS (UNII: U182GP2CF3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
C30-45 ALKYL METHICONE (UNII: NFX970DSI2)	

C30-45 OLEFIN (UNII: 6DWD51M008)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
DIMETHICONE (UNII: 92RU3N3Y10)
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
ISOSTEARIC ACID (UNII: X33R8U0062)
PAPAIN (UNII: A236A06Y32)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
TRIMETHYLSILOXYSILICATE (M/Q 1.0-1.2) (UNII: 78GX033D7I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-245-01	30 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M020	05/07/2022	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-245)

Establishment

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-245)