

TOPIX MINERAL BRIGHTENING AND CORRECTING EYE MAKE-UP SPF 50- zinc oxide and titanium dioxide lotion

Topiderm, Inc.

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.

Topix Mineral Brightening and Correcting Eye Make-up SPF 50

Drug Facts

Active ingredient	Purpose
Zinc Oxide 6.5%	Sunscreen
Titanium Oxide 6.4%	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.

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 Immediately.

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- **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 & other sunscreen measures including:
 - Limit time in the sun especially from 10 a.m. to 2 p.m.
 - Wear long-sleeve shirts, pants, hats, and sunglasses
 - Children under 6 months of age: Ask a doctor.

Other information

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

Inactive Ingredients

Purified Water, Caprylyl Methicone, Cetyl Diglyceryl Tris(trimethylsiloxy)silylethyl Dimethicone, Dimethicone Crosspolymer, Glycerin, Isododecane, Dimethicone, Alumina, Hydrogen Dimethicone, HDI/Trimethylol Hexyllactone Crosspolymer, Iron Oxides, Tin Oxide, Sodium Hyaluronate, Acetyl Hexapeptide-8, Leontopodium Alpinum Callus Culture Extract, Dunaliella Salina Extract, Macrocystis Pyrifera (Kelp) Extract, Panthenol, Tocopheryl Acetate, Palmitoyl Tripeptide-5, Hydrolyzed Vegetable Protein, Ascophyllum Nodosum Extract, Asparagopsis Armata Extract, Sucrose, Xanthan Gum, Mica, Silica, PVP, Triethoxycaprylylsilane, Sorbitol, Phenyl Trimethicone, Sodium Chloride, Phenoxyethanol, Disodium EDTA, Potassium Sorbate.

PRINCIPAL DISPLAY PANEL - 8.5 ml Tube Carton

AGE DEFENSE
FOR THE EYES

5-IN-1

BROAD SPECTRUM UVA/UVB SPF 50+

WATER/SWEAT RESISTANT (80 MIN)

Net 0.29 fl. oz. (8.5 ml)

MINERAL EYE TREATMENT SPF 50+

AGE DEFENSE FOR THE EYES

5-IN-1

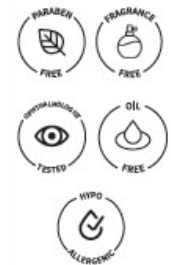
Broad spectrum SPF 50+ mineral eye treatment offers multi-benefit protection & correction against the visible signs of aging. Improve the look of dark circles, puffiness, sagging skin and fine lines around the delicate eye area immediately & over time. May be applied as a concealer or concealing primer.

BENEFITS:

5-IN-1 AGE DEFENSE

- ✓ PROTECT
- ✓ BRIGHTEN
- ✓ CONCEAL
- ✓ SOOTHE
- ✓ HYDRATE

- Evenly distributed broad spectrum UVA/UVB protection
- Provides active protection while sweating or swimming
- Non-migrating, hybrid formula stays in place
- Corrects visible discoloration, dark circles and minor imperfections
- Cooling applicator + antioxidants depuffs and soothes
- Prevents moisture loss around the eye area



HOW TO USE:
Dispense a half pump onto the cooling applicator & apply to both eyes. Using the applicator, gently smooth product under eye and along the orbital bone. Gently pat excess product in with fingertips to ensure even and perfected coverage. Non-migrating, hybrid formula stays in place. Reapply throughout the day for continued protection & to refresh coverage as needed.

Ophthalmologist tested for safe use around the eye.

- Peptide Blend
- Edelweiss Flower Extract
- Kelp Extract
- Vegetable Protein
- Hyaluronic Acid
- Titanium Dioxide

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R0520 Made in U.S.A. 1216MB

BROAD SPECTRUM UVA/UVB SPF 50+
PROTECT + CONCEAL
WATER/SWEAT RESISTANT (80 MIN)

Net 0.29 fl. oz. (8.5 ml)



TOPIX MINERAL BRIGHTENING AND CORRECTING EYE MAKE-UP SPF 50

zinc oxide and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-121
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	65 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETYL DIGLYCERYL TRIS(TRIMETHYLSILOXY)SILYLETHYL DIMETHICONE (3500 MM2/S) (UNII: KB7T6C99UP)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISODODECANE (UNII: A8289P68Y2)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FERROUS OXIDE (UNII: G7036X8B5H)	
STANNOUS OXIDE (UNII: JB2MV9I3LS)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWL)	
LEONTOPODIUM NIVALE SUBSP. ALPINUM ROOT (UNII: SDW6SS1K6I)	
DUNALIELLA SALINA (UNII: F401DKI9A6)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
ASCOPHYLLUM NODOSUM (UNII: 168S4EO8YJ)	
ASPARAGOPSIS ARMATA (UNII: 2936KN6I1G)	

SUCROSE (UNII: C151H8M554)
XANTHAN GUM (UNII: TTV12P4NEE)
MICA (UNII: V8A1AW0880)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLY(4-VINYLPYRIDINE-N-OXIDE) (UNII: 2I40HY84KZ)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
SORBITOL (UNII: 506T60A25R)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
EDETATE DISODIUM (UNII: 7FLD91C86K)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-121-01	8.5 mL in 1 TUBE; Type 0: Not a Combination Product	01/24/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/24/2021	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-121)

Revised: 3/2023

Topiderm, Inc.