ESSENTIAL MOISTURIZING SUNSCREEN- zinc oxide 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.

Essential Moisturizing Sunscreen

Drug Facts

Active ingredient	***Purpose***
Zinc Oxide 14.8%	Sunscreen
Octinoxate 7.5%	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, Diethylhexyl Succinate, Octyldodecyl Neopentanoate, Cetearyl Glucoside, Cetyl Ethylhexanoate, Polyisobutene, Sodium Hyaluronate, Tocopheryl Acetate, Caffeine, Xanthan Gum, Butylene Glycol, Triethoxycaprylylsilane, Oleth-3 Phosphate, Ethylhexyl Stearate, Dimethicone, Sucrose, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-7 Trimethylolpropane Coconut Ether, Panthenol, Phenoxyethanol, Disodium EDTA.

PRINCIPAL DISPLAY PANEL - 63 g Bottle Label

REPLENiX®
SUNSCREEN

ESSENTIAL
MOISTURIZING
SPF 50

14.8% Micronized Zinc Oxide
Hydrating Hyaluronic Acid
Quick-absorbing Application

BROAD SPECTRUM UVA/UVB SPF 50

Net wt. 2.22 oz. (63 g)

TOPIX PHARMACEUTICALS, INC. N. AMITYVILLE, NY 11701

REPLENIX®

SUNSCREEN

ESSENTIAL MOISTURIZING SPF 50

14.8% Micronized Zinc Oxide

Hydrating Hyaluronic Acid

Quick-absorbing Application

BROAD SPECTRUM UVA/UVB SPF 50

Net wt. 2.22 oz. (63 g)

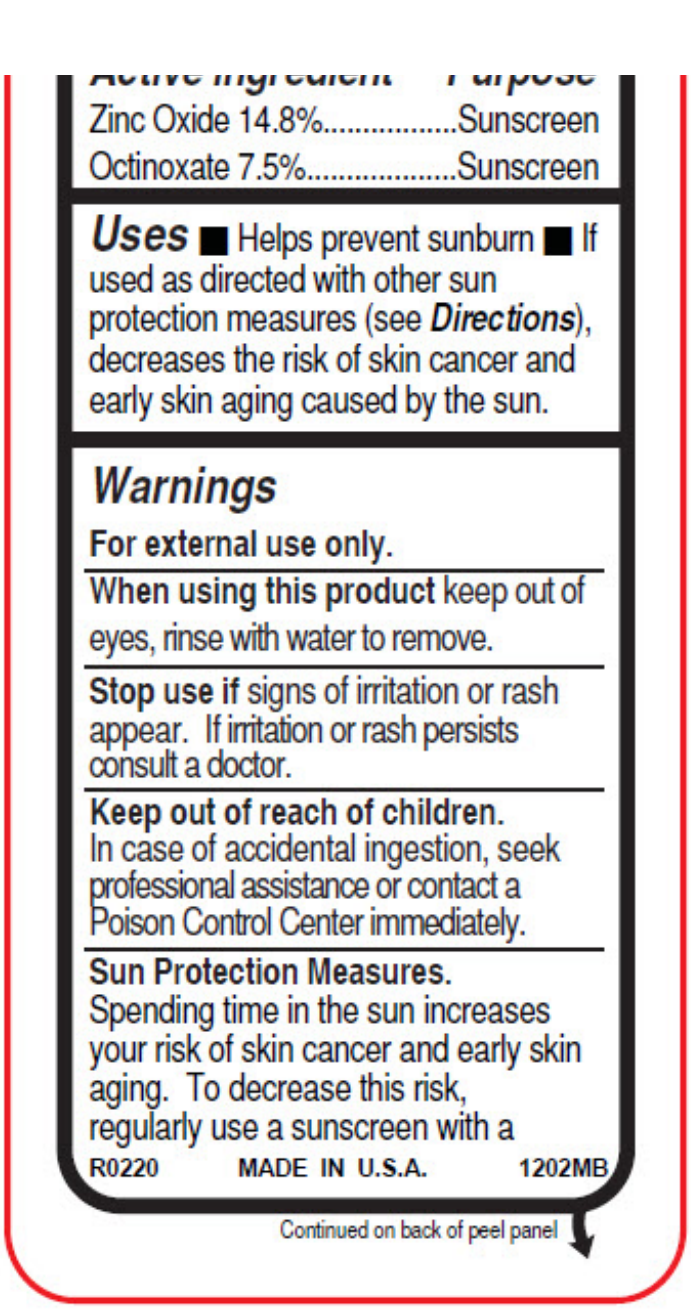
TOPIX PHARMACEUTICALS, INC. N. AMITYVILLE, NY 11701

Drug Facts

Active ingredient Purpose

Drug Facts (continued)

Warnings (continued)



ESSENTIAL MOISTURIZING SUNSCREEN

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51326-122
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	148 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
POLYISOBUTYLENE (2300 MW) (UNII: DSQ2V1DD1K)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAFFEINE (UNII: 3G6A5W338E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
1,3-BUTANEDITHIOL (UNII: 85VJA9KBCH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SUCROSE (UNII: C151H8M554)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
PEG-7 TRIMETHYLOLPROPANE COCONUT ETHER (UNII: MVJ3AD73GG)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-122-20	63 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/09/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/09/2021	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-122)