

ANTIOXIDANT SUNSCREEN SPF 40- octinoxate and zinc oxide lotion Topiderm, Inc.

Vit C Antioxidant Sunscreen SPF 40

Drug Facts

Active ingredients	Purpose
Octinoxate 7.5%	Sunscreen
Zinc Oxide 7.0%	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 15 minutes before sun exposure
- Re-apply after 80 minutes of swimming or sweating, anytime after towel drying, or at least every 2 hours
- 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

Ascorbic Acid, Ascorbyl Palmitate, Butylene Glycol, Camellia Sinensis (Green Tea) Leaf Extract, C12-15 Alkyl Benzoate, C13-14 Isoparaffin, Ceresin, Chitosan, Cyclomethicone, Diazolidinyl Urea, Disodium EDTA, Laureth-7, Lauryl PEG/PPG-18/18 Methicone, Methylparaben, Phospholipids, Polyacrylamide, Propyl Gallate, Propylene Glycol, Propylparaben, Purified Water, Retinyl Palmitate, Sodium Chloride, Superdioxide

Dismutase, Tocopheryl Acetate, Ubiquinone (Co Q-10).

PRINCIPAL DISPLAY PANEL - 105 ml Bottle Label

CITRIX®

VITAMIN C
ANTIOXIDANT SUNSCREEN
BROAD SPECTRUM SPF 40

UVA & UVB Protection
Micronized Zinc Oxide
Water Resistant (80 minutes)

POLYMER MATRIX TECHNOLOGY

Net 3.5 fl. oz. (105 ml)
Topix Pharmaceuticals, Inc. | N. Amityville, NY 11701

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■ **Sun Protection Measures.** Spending

R0519

Made in U.S.A.

829

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ANTIOXIDANT SUNSCREEN SPF 40

octinoxate and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51326-829
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)
CERESIN (UNII: Q1LS2UJO3A)
CHITOSAN LOW MOLECULAR WEIGHT (20-200 MPA.S) (UNII: SBD1A2I75N)
CYCLOMETHICONE (UNII: NMQ347994Z)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
LAURETH-7 (UNII: Z95S6G8201)
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)
METHYLPARABEN (UNII: A2I8C7HI9T)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWW)
PROPYL GALLATE (UNII: 8D45NN7V92)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0K00R)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SUPEROXIDE DISMUTASE (SACCHAROMYCES CEREVISIAE) (UNII: W2T4YRA9AD)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
UBIDECARENONE (UNII: EJ27X76M46)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-829-03	105 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/28/2000	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M020	07/28/2000	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-829)

Establishment

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-829)

