

NATURAL SUN ECO OIL CLEAR SUNSCREEN CREAM 50 SPF- ensulizole and zinc oxide cream cream

THEFACESHOP CO., LTD.

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.

NATURAL SUN ECO Oil Clear Sunscreen Cream 50+ PA+++ 31500193

Active Ingredients

Ensulizole 3.7 %

Zinc Oxide 12.9 %

Purpose

Sunscreen

Sunscreen

Uses

Helps prevent sunburn.

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 right away.

Directions

Apply generously and evenly 15 minutes before sun exposure.

Children under 6 months of age: Ask a doctor.

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

Reapply at least every 2 hours.

Use a water-resistant sunscreen if swimming or sweating.

Apply an adequate amount on the face and neck at the final stage of skincare.

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

May stain or damage some fabrics or surfaces.

Inactive Ingredients

WATER,CYCLOPENTASILOXANE, PEG-10 DIMETHICONE, DIMETHICONE/METHICONE COPOLYMER, HEXYL LAURATE, METHICONE, ALUMINA, PROPANEDIOL, DICAPRYLYL

NATURAL SUN ECO OIL CLEAR SUNSCREEN CREAM 50 SPF

ensulizole and zinc oxide cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51523-193
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	1.85 g in 50 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6.45 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51523-193-06	1 in 1 CARTON	10/01/2015	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2015	

Labeler - THEFACESHOP CO., LTD. (688329416)

Registrant - THEFACESHOP NORTH AMERICA, INC. (620459193)

Establishment

Name	Address	ID/FEI	Business Operations
THEFACESHOP CO., LTD.		688329416	label(51523-193)

Revised: 10/2015

THEFACESHOP CO., LTD.