

CREAM- zinc oxide cream
Oxygen Development LLC

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.

KYPRIS POT OF SHADE HELIOTROPIC BROAD SPECTRUM SPF30 SUNSCREEN & PRIMER

Active Ingredients

Zinc Oxide 20%

Purpose

Sunscreen

uses

Help prevent sunburns

if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun.

Warnings

For external use only.

Do not use

Do not use on damaged or broken skin.

When using this product

When using this product, keep out of eyes. Rinse with water to remove.

Stop use

stop use and ask a doctor if rash occurs

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Directions

Apply liberally 15 minutes before sun exposure.

Reapply at least every two hours

Use a water resistant sunscreen if swimming or sweating.

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 value 15 or higher and other sun protection measures including:

Limit time in the sun, especially from 10am to 2 pm

Wear long-sleeved shirt, pants, hats, and sunglasses

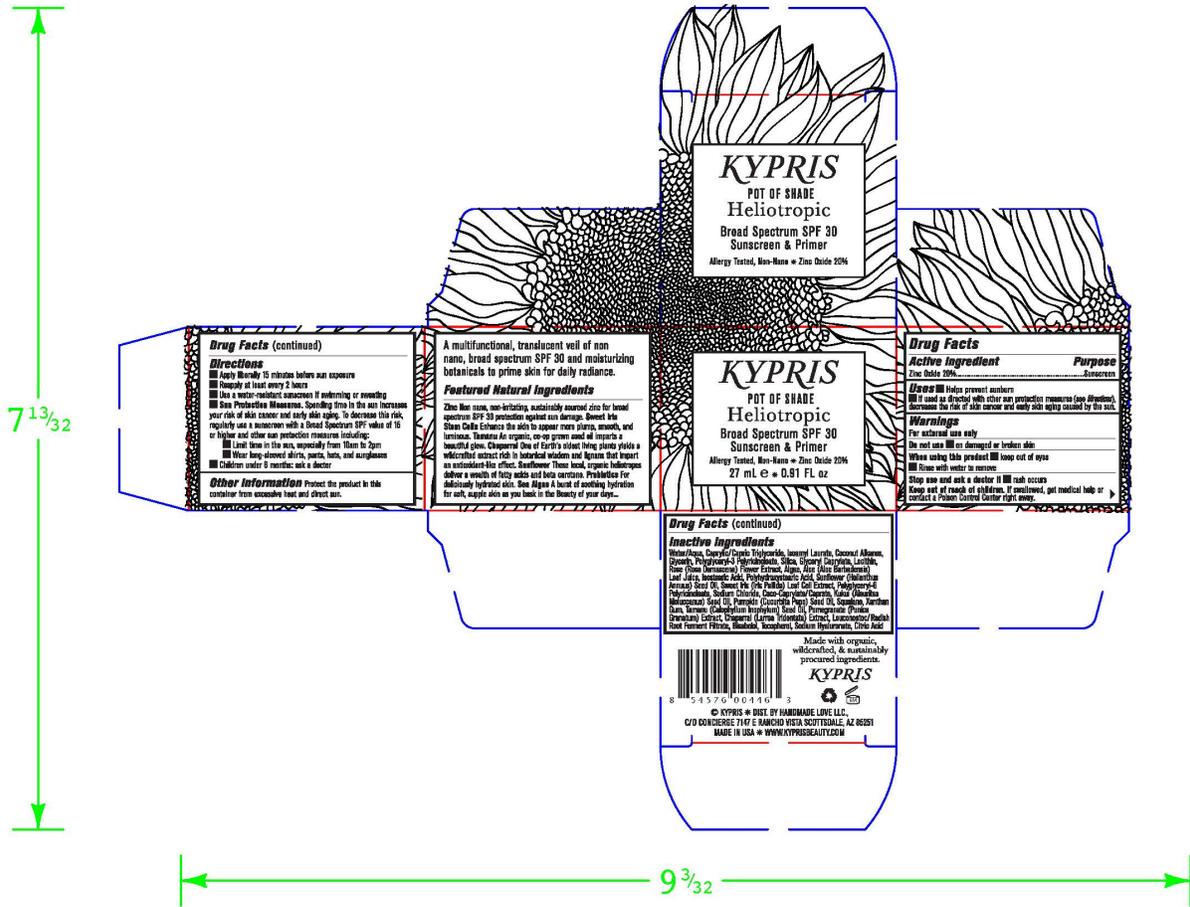
Children under 6 months: ask a doctor

Other information

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

Water/Aqua, Caprylic/Capric Triglyceride, Isoamyl Laurate, Coconut Alkanes, Glycerin, Polyglyceryl-3 Polyricinoleate, Silica, Glyceryl Caprylate, Lecithin, Rose (Rosa Damascena) Flower Extract, Algae, Aloe (Aloe Barbadensis) Leaf Juice, Isostearic Acid, Polyhydroxystearic Acid, Sunflower (Helianthus Annuus) Seed Oil, Sweet Iris (Iris Pallida) Leaf Cell Extract, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Coco-Caprylate/Caprate, Kukui (Aleurites Moluccanus) Seed Oil, Pumpkin (Cucurbita Pepo) Seed Oil, Squalane, Xanthan Gum, Tamanu (Calophyllum Inophyllum) Seed Oil, Pomegranate (Punica Granatum) Extract, Chaparral (Larrea Tridentata) Extract, Leuconostoc/Radish Root Ferment Filtrate, Bisabolol, Tocopherol, Sodium Hyaluronate, Citric Acid

Secondary package



27 ml 61354-033-01

CREAM

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61354-033
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19.72 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
COCONUT ALKANES (UNII: 1E5KJY107T)	
WATER (UNII: 059QF0KO0R)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
ISOAMYL LAURATE (UNII: M1SLX00M3M)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
ISOSTEARIC ACID (UNII: X33R8U0062)
ROSA X DAMASCENA FLOWER (UNII: JWB78P295A)
SUNFLOWER OIL (UNII: 3W1JG795YI)
POLYGLYCERYL-6 POLYRICINOLEATE (UNII: YPM0ZOC2HR)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)
GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-033-01	1 in 1 CARTON	02/22/2021	
1		3 mg in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/22/2021	

Labeler - Oxygen Development LLC (137098492)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-033)

Revised: 2/2023

Oxygen Development LLC