

**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.*

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**KYPRIS POT OF SHADE HELIOTROPIC SPF 30 UVA+UVB SUNSCREEN**  
**PROTECTION SOLAIRE PRIMER**

**Active Ingredient**

Zinc Oxide 20%

**Purpose**

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 swallowed, get medical help or contact a Poison Control Center right away.

## Directions

Apply liberally 15 minutes before sun exposure.

Reapply at least every 2 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 of 15 or higher and other sun protection measures including:

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

Wear long-sleeved shirts, 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.

## Inactive Ingredients

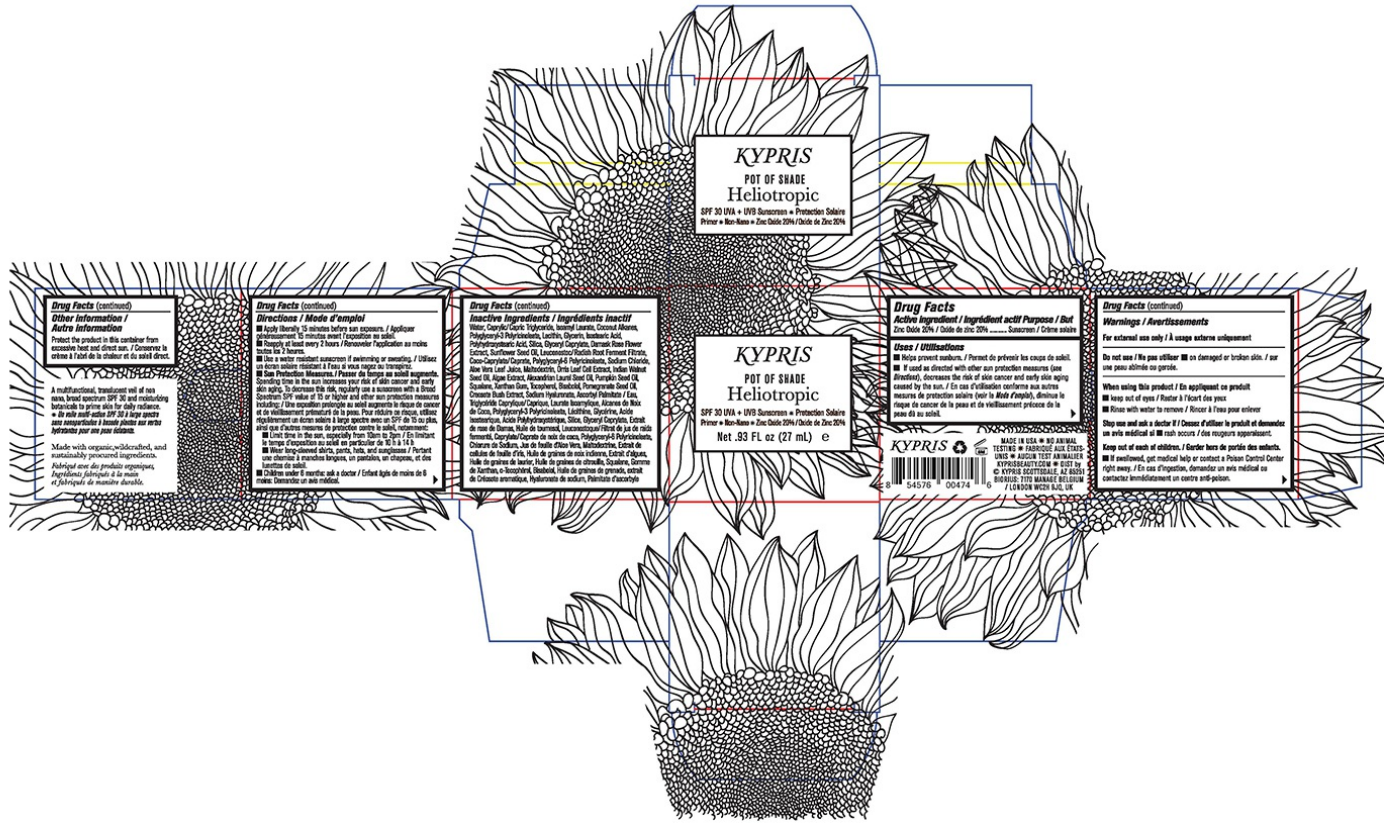
Water, Caprylic/Capric Triglyceride, Isoamyl Laurate, Coconut Alkanes, Polyglyceryl-3 Polyricinoleate, Lecithin, Glycerin, Isostearic Acid, Polyhydroxystearic Acid, Silica, Glyceryl Caprylate, Damask Rose Flower Extract, Sunflower Seed Oil, Leuconostoc/Radish Root Ferment Filtrate, Coco-Caprylate/Caprates, Polyglyceryl-6 Polyricinoleate, Sodium Chloride, Aloe Vera Leaf Juice, Maltodextrin, Orris Leaf Cell Extract, Indian Walnut Seed Oil, Algae Extract, Alexandrian Laurel Seed Oil, Pumpkin Seed Oil, Squalane, Xanthan Gum, Tocopherol, Bisabolol, Pomegranate Seed Oil, Creosote Bush Extract, Sodium Hyaluronate, Ascorbyl Palmitate.

## Primary size 27ml

Apply generously 15 minutes before sun exposure \* For external use only \* Do not use on damaged or broken skin \* Keep out of eyes \* Rinse with water to remove \* Keep out of reach of children \* If swallowed seek medical help or contact Poison Control / Appliquez généreusement 15 minutes avant l'exposition au soleil \* À usage externe uniquement \* Ne pas utiliser sur une peau abîmée ou gercée \* En appliquant ce produit, veillez à ce qu'il n'entre pas en contact avec vos yeux \* Rincez à l'eau pour le retirer \* Garder hors de portée des enfants \* En cas d'ingestion, demandez un avis médical ou contactez immédiatement un centre anti-poison. \* ♻️



## Secondary 27ml

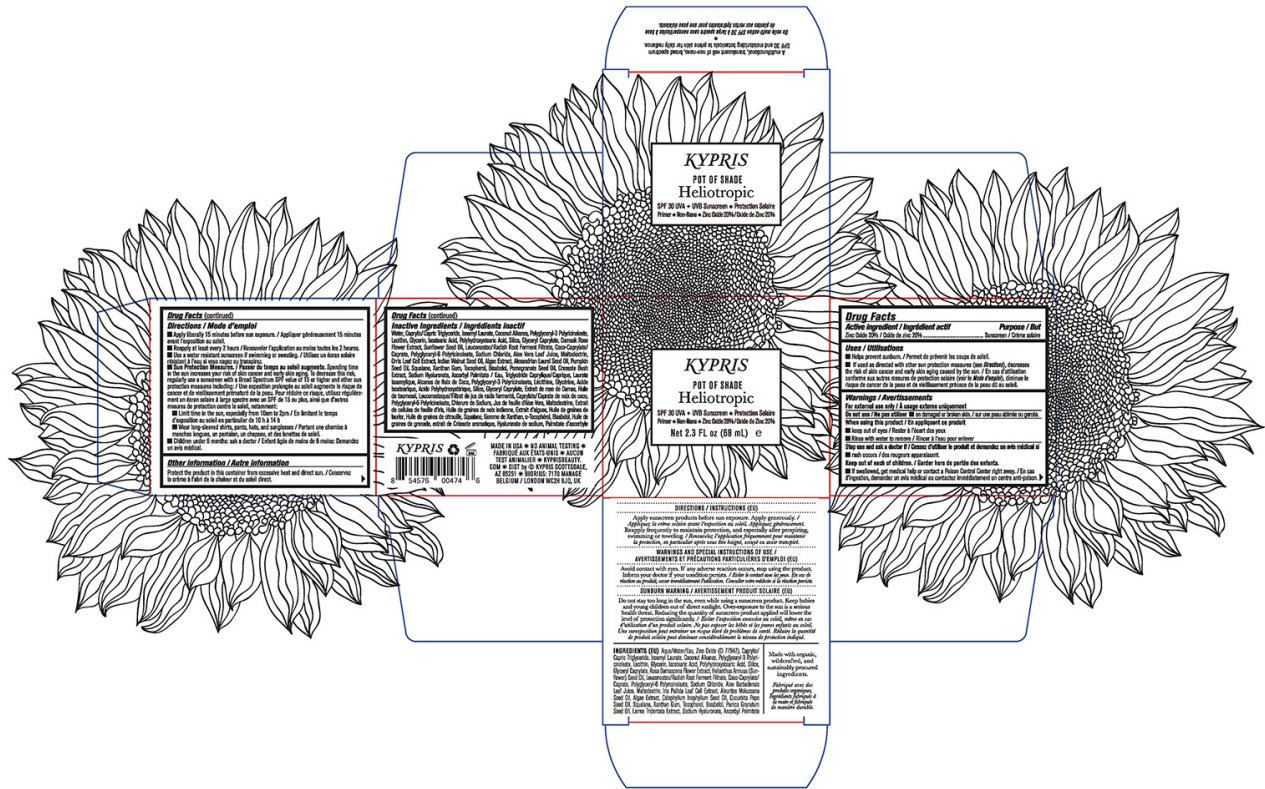


## Primary 68ml

Apply generously 15 minutes before sun exposure \* For external use only \* Do not use on damaged or broken skin \* Keep out of eyes \* Rinse with water to remove \* Keep out of reach of children \* If swallowed seek medical help or contact Poison Control / Appliquer généreusement 15 minutes avant l'exposition au soleil \* À usage externe uniquement \* Ne pas utiliser sur une peau abîmée ou gercée \* En appliquant ce produit, veillez à ce qu'il n'entre pas en contact avec vos yeux \* Rincez à l'eau pour le retirer \* Garder hors de portée des enfants \* En cas d'ingestion, demandez un avis médical ou contactez immédiatement un centre anti-poison. ☞



## Secondary 68ml



# CREAM

zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61354-030
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)	
<b>WATER</b> (UNII: 059QF0KOOR)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>COCONUT ALKANES</b> (UNII: 1E5KJY107T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	

<b>GLYCERYL CAPRATE</b> (UNII: 197M6VFC1W)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>POLYGLYCERYL-6 POLYRICINOLEATE</b> (UNII: YPM0ZOC2HR)	
<b>ISOAMYL LAURATE</b> (UNII: M1SLX00M3M)	
<b>ROSA DAMASCENA FLOWER</b> (UNII: JWB78P295A)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-030-04	1 in 1 CARTON	02/22/2021	
1	NDC:61354-030-02	68 mg in 1 JAR; Type 0: Not a Combination Product		
2	NDC:61354-030-05	1 in 1 CARTON	02/22/2021	
2	NDC:61354-030-03	27 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 not final	part352	02/22/2021	

**Labeler** - Oxygen Development LLC (137098492)

### Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-030)

Revised: 2/2023

Oxygen Development LLC