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 PRIME AND PROTECT BROAD SPECTRUM SPF 30

Directions

Apply liberally 15 minutes before sun exposure.
Reapply at least every two hours
Use a water resistant sunscreen if swimming or sweating.

Active Ingredients

Zinc Oxide 20%

Warnings

For external use only.

Do not use

Do not use on damaged on broken skin.

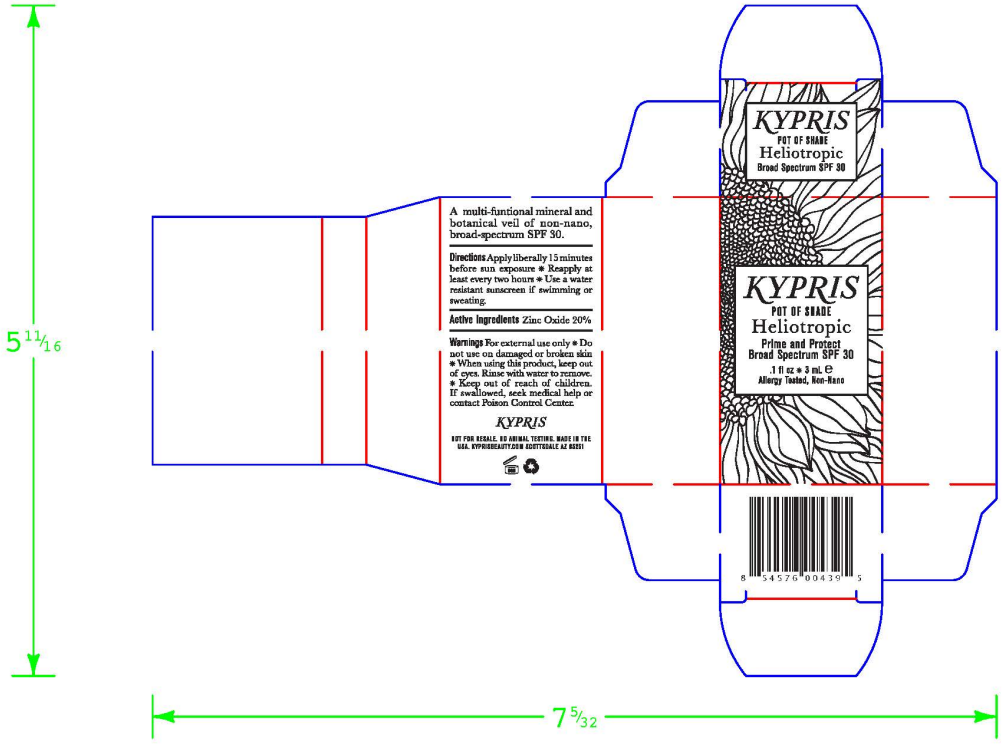
When using this product

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

Keep out of reach of children

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

Secondary 3ml



CREAM

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-030
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:61354-030-06	1 in 1 CARTON	02/22/2021	
1	NDC:61354-030-01	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(61354-030)

Revised: 2/2023 Oxygen Development LLC