

**KINESYS- zinc oxide cream**  
**Wilc Healthcare Inc**

*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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**KINeSYS Performance Sunscreen CLEAR ZINC**

**Active Ingredient**

Zinc Oxide 25% w/w

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

**Directions**

- Apply generously and spread evenly to all exposed skin 20 minutes before sun exposure

**Reapply:**

- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

**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 sun protection measures including:

- limit time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses

**children under 6 months:** Ask a doctor

### Inactive Ingredients

Aloe Barbadosensis Leaf Extract, Bisabolol, Beeswax, Capric/Caprylic Triglyceride, Coconut Oil, Peppermint Oil, Polyhydroxystearic acid and Isostearic acid, Rosemary Leaf Oil, Sunflower seed oil, Tocopherols.

### Other Information

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

### Questions or Comments?

Call toll free 1.888.KINeSYS [546.3797] [www.kinesysactive.com](http://www.kinesysactive.com)

### PRINCIPAL DISPLAY PANEL

NDC 61481-0036-2

KINeSYS Performance SUNSCREEN

CLEAR ZINC WITH 25% NATURAL ZINC OXIDE

BROAD SPECTRUM SPF 30

UVA+UVB

PEPPERMINT AND ROSEMARY

80 MINS WATER AND SWEAT RESISTANT

2 OZ (60 g)



## KINESYS

zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61481-0036
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	25 g in 100 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
LEVOMENOL (UNII: 24WE03BX2T)				
COCONUT OIL (UNII: Q9L0O73W7L)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
ISOSTEARIC ACID (UNII: X33R8U0062)				
ROSEMARY OIL (UNII: 8LGU7VM393)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
TOCOPHEROL (UNII: R0ZB2556P8)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:61481-0036-2	60 g in 1 JAR; Type 0: Not a Combination Product	09/26/2018	
<b>Marketing Information</b>				
<b>Marketing Category</b>		<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH NOT FINAL		part348	09/26/2018	

**Labeler** - Wilc Healthcare Inc (203499140)

**Registrant** - Wilc Healthcare Inc (203499140)

**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmeaceutical Research Laboratory Inc		256797309	manufacture(61481-0036)

Revised: 9/2018

Wilc Healthcare Inc