

KARA VITA MOISTURIZING SUNSCREEN WITH DNARESCUE- oxybenzone, avobenzone, octinoxate, octisalate, and homosalate cream

Kara Vita, 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.

Karavita

Moisturizing SPF 29 Active with DNArescue™

Drug Facts

Active ingredients

Benzophenone-3 6.0%

Butyl Methoxydibenzoylmethane 3.0%

Ethylhexyl Methoxycinnamate 7.5%

Ethylhexyl Salicylate 5.0%

Homosalate 6.0%

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 liberally 15 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

purified water, potassium cetyl phosphate, sorbitol, dicaprylyl maleate, alcohol, lecithin, artemia extract, tocopheryl acetate, aloe barbadensis leaf juice, dimethicone, carbomer, cetyl alcohol, methylparaben, propylparaben, triethanolamine

Manufactured for Kara Vita by:

Dermazone Solutions

St. Petersburg, FL 33713

1.727.456.7560

PRINCIPAL DISPLAY PANEL - 113 g Bottle Carton

KARA VITA

**Moisturizing
Sunscreen with
DNArescue™**

**SPF
29 ACTIVE**

BROAD SPECTRUM

**WATER RESISTANT
(80 MINUTES)**

4 OZ (113 g)

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P019_0114

DESCRIPTION:

Moisturizing Sunscreen with DNArescue™ SPF 29 ACTIVE shields the skin from UVA and UVB rays with broad spectrum protection while it unlocks the skin's ability to preserve the integrity of its DNA. Daily use prior to sun exposure helps skin to resist cell death and damage caused by the sun. This synergistic blend of ingredients affect the most fundamental element within the skin: the DNA blueprint. Protecting DNA from damage is vital for maintaining younger-looking skin.

BENEFITS:

- Time-released all-natural Lyphazomes®
- Durable for active lifestyles
- UVA/UVB broad spectrum protection
- Day-long hydrating and moisturizing protection
- Reduces the risk of skin cancer and early skin aging, as well as helps prevent sunburn if used as directed with other sun protection measures
- Dermatologist recommended
- Fragrance free and PABA free

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Moisturizing
Sunscreen with
DNArescue™

SPF 29 ACTIVE

BROAD SPECTRUM

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(80 MINUTES)

4 OZ (113 g)

Produced at
Pharmaceutical Standards with
Lyphazome® Technology
Made in the U.S.A.

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St. Petersburg, FL 33713
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www.karavita.com

KARA VITA MOISTURIZING SUNSCREEN WITH DNARESCUE

oxybenzone, avobenzone, octinoxate, octisalate, and homosalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68572-6018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	60 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	60 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
potassium cetyl phosphate (UNII: 03KCY6P7UT)	
sorbitol (UNII: 506T60A25R)	
dioctyl maleate (UNII: OD88G8439L)	
alcohol (UNII: 3K9958V90M)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
aloe vera leaf (UNII: ZY81Z83H0X)	
dimethicone (UNII: 92RU3N3Y1O)	
cetyl alcohol (UNII: 936JST6JCN)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68572-6018-4	1 in 1 CARTON	10/15/2015	
1		113 g in 1 BOTTLE; 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	10/15/2015	

Labeler - Kara Vita, Inc. (140693388)

Establishment

Name	Address	ID/FEI	Business Operations
Deramzone Solutions, Inc.		136 1168 65	MANUFACTURE(68572-6018)

Revised: 11/2018

Kara Vita, Inc.