

**CARAGALA - BOTANICAL DEFENSE DAY CREAM BROAD SPECTRUM SPF 30
SUNSCREEN- octinoxate and zinc oxide lotion
Cosmetic Solutions 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.

**CaraGala - Botanical Defense Day Cream Broad Spectrum SPF 30 Sunscreen
DRUG FACTS:**

ACTIVE INGREDIENTS

Octinoxate 7.5%, Zinc Oxide 10.0%}

Purpose

Sunscreen

USES

Helps prevent sunburn.

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 each of children.

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

DIRECTIONS

Apply to all skin exposed to the sun. Apply liberally and evenly 15 minutes before sun exposure. Reapply at least every 2 hours. If swimming or sweating, use water resistant sunscreen.

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. Decrease this risk, by regularly using sunscreen with a Broad Spectrum SPF 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 am - 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses

Children under 6 months: Ask a doctor

INACTIVE INGREDIENTS

Water (Aqua), Butyloctyl Salicylate, Glycerin, Dimethicone, Styrene/Acrylates Copolymer, Coco-Caprylate/Caprates, Caprylic/Capric Triglyceride, VP/Eicosene Copolymer, Carthamus Tinctorius Oleosomes, Elettaria Cardamomum Seed Extract, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate, Perilla Frutescens Extract, Pyrus Malus (Apple) Fruit Extract, Rose Extract, Santalum Album Extract, Camellia Sinensis Leaf Extract, Anthemis Nobilis Flower Extract, Cananga Odorata Flower Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Cucumis Melo (Melon) Fruit Extract, Cucumis Sativus Fruit Extract, Jasminum Officinale Flower/Leaf Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Rubus Idaeus (Raspberry) Fruit Extract, Polygonum Aviculare Extract, Vitis Vinifera Fruit Cell Extract, Propanediol, Cetearyl Alcohol, Pentylene Glycol, Arachidyl Alcohol, Polyhydroxystearic Acid, Coco-Glucoside, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Behenyl Alcohol, Xanthan Gum, Triethoxycaprylylsilane, Arachidyl Glucoside, Phenethyl Alcohol, Caprylyl Glycol.

OTHER INFORMATION

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

PRINCIPAL DISPLAY PANEL - 60 G Tube Carton

Cara Gala

Botanical

Defense

Day Cream

Broad Spectrum

SPF 30

Sunscreen

SUNSCREEN

NET WT. 2 OZ. (60G)

DRUG FACTS:

ACTIVE INGREDIENTS: Purpose
Oxinoate 75%, Zinc Oxide 10.0% ---- Sunscreen

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Zinc Oxide

Works to seal your skin with a protective barrier to keep from losing moisture.

Polygonum Aviculare (Knotgrass) Extract

A botanical extract which fights infrared-induced skin aging and has been shown to increase firmness.

Camellia Sinensis Leaf (Green Tea) Extract

Full of powerful antioxidant properties, this extract helps to combat the effects of environmental damage.

Perilla Frutescens (Chinese Basil) Extract

This extract is full of polyphenols which protect against UV radiation and enhance skin cell growth.

CaraGala



Botanical Defense Day Cream

Broad Spectrum SPF 30 Sunscreen

SUNSCREEN
NET WT. 2 OZ. (60G)

Scan code to learn more

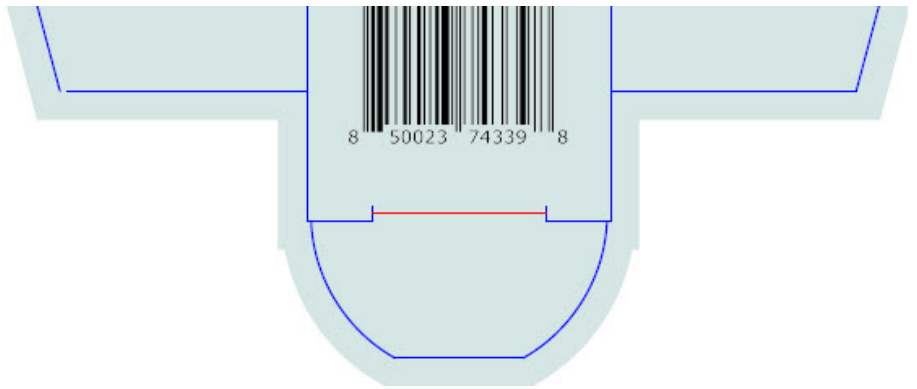


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MANUFACTURED FOR
CARAGALA LLC
ENGLEWOOD, CO 80112
CARAGALA.COM





CARAGALA - BOTANICAL DEFENSE DAY CREAM BROAD SPECTRUM SPF 30 SUNSCREEN

octinoxate and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66163-0302
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butyloctyl Salicylate (UNII: 2EH13UN8D3)	
Glycerin (UNII: PDC6A3C0OX)	
Dimethicone (UNII: 92RU3N3Y1O)	
Styrene/Acrylamide Copolymer (500000 MW) (UNII: 5Z4DPO246A)	
Cocoyl Caprylocaprate (UNII: 8D9H4QU99H)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Carthamus Tinctorius Seed Oleosomes (UNII: 9S60Q72309)	
Cardamom (UNII: 8BC4CUT4JL)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Perilla Frutescens Seed (UNII: 8M62PUD356)	
Apple (UNII: B423VGH5S9)	
Santalum Album Seed (UNII: 7RZT0U509Y)	
Green Tea Leaf (UNII: W2ZU1RY8B0)	
Chamaemelum Nobile Flower (UNII: O2T154T6OG)	
Cananga Odorata Flower (UNII: 76GTF6Z97M)	
Orange Peel (UNII: T19T76XD44)	
Muskmelon (UNII: ZV095H5633)	

Jasminum Officinale Flower (UNII: 0Q8K841432)
Lavandula Angustifolia Subsp. Angustifolia Flowering Top (UNII: 9YT4B71U8P)
Raspberry (UNII: 4N14V5R27W)
Polygonum Aviculare Top (UNII: ZCD6009IUF)
Propanediol (UNII: 5965N8W85T)
Cetostearyl Alcohol (UNII: 2DMT128M1S)
Pentylene Glycol (UNII: 50C1307PZG)
Arachidyl Alcohol (UNII: 1QR1QRA9BU)
Coco Glucoside (UNII: ICS790225B)
Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)
Docosanol (UNII: 9G10E216XY)
Xanthan Gum (UNII: TTV12P4NEE)
Triethoxycaprylylsilane (UNII: LDC331P08E)
Arachidyl Glucoside (UNII: 6JWV35JOOJ)
Phenylethyl Alcohol (UNII: ML9LGA7468)
Caprylyl Glycol (UNII: 00YIU5438U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66163-0302-1	1 in 1 CARTON	04/01/2022	
1		60 mL in 1 TUBE; 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	04/01/2022	

Labeler - Cosmetic Solutions LLC (807907928)