

CELAZOME MOISTURIZING SPF 29 ACTIVE WITH DNARESCUE- oxybenzone, octinoxate, octisalate, and homosalate cream

Dermazone Solutions, 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.

celazome®

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 Celazome[®] by:

Dermazone Solutions

St. Petersburg, FL 33713

PRINCIPAL DISPLAY PANEL - 113 g Bottle Carton

celazome[®]

clinical skin care

DNARescue[™]

Moisturizing Sunscreen

Clinical Skin Care with

Lyphazome[®] Nanotechnology

SPF 29 ACTIVE

BROAD SPECTRUM

WATER RESISTANT

(80 MINUTES)

4 OZ (113 g)



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DESCRIPTION:

DNARescue™ Moisturizing Sunscreen 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
- Daylong 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

celazome®
clinical skin care

**DNARescue™
Moisturizing Sunscreen**

Clinical Skin Care with
Lyphazome® Nanotechnology

**SPF 29 ACTIVE
BROAD SPECTRUM**

WATER RESISTANT
(80 MINUTES)

4 OZ (113 g)

Produced at
Pharmaceutical Standards with
Lyphazome® Nanotechnology

Manufactured for Celazome® by:
Dermazone Solutions
St. Petersburg, FL 33713
1.800.253.5115

www.celazomeskin.com

Made in the U.S.A.

CELAZOME MOISTURIZING SPF 29 ACTIVE WITH DNARESCUE

oxybenzone, octinoxate, octisalate, and homosalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58466-108
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
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	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
dioctyl maleate (UNII: OD88G8439L)	
alcohol (UNII: 3K9958V90M)	
sorbitol (UNII: 506T60A25R)	
Diethanolamine Cetyl Phosphate (UNII: 4UG0316V9S)	
aloe vera leaf (UNII: ZY81Z83H0X)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
dimethicone (UNII: 92RU3N3Y1O)	
cetyl alcohol (UNII: 936JST6JCN)	
trolamine (UNII: 9O3K93S3TK)	
propylparaben (UNII: Z8IX2SC1OH)	
methylparaben (UNII: A218C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58466-108-04	1 in 1 CARTON	10/01/2015	
1		113 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC MONOGRAPH FINAL	part352	10/01/2015	
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Labeler - Dermazone Solutions, Inc. (136116865)

Establishment

Name	Address	ID/FEI	Business Operations
Deramzone Solutions, Inc.		136116865	MANUFACTURE(58466-108)

Revised: 11/2018

Dermazone Solutions, Inc.