

CELAZOME MOISTURIZING SPF 30 ACTIVE- 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 30 Active

Drug Facts

Active ingredients

Benzophenone-3 5.0%

Ethylhexyl Methoxycinnamate 7.5%

Ethylhexyl Salicylate 5.0%

Homosalate 5.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

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

Manufactured for Celazome[®] by:

Dermazone Solutions

St. Petersburg, FL 33713

PRINCIPAL DISPLAY PANEL - 113 g Bottle Carton

celazome[®]

clinical skin care

Moisturizing Sunscreen

Clinical Skin Care with
Lyphazome[®] Technology

SPF 30 ACTIVE

SPORT

WATER RESISTANT
(80 MINUTES)

4 OZ (113 g)



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Produced at
Pharmaceutical Standards with
Lyphazome[®] Technology

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

www.celazomeskin.com

Made in the U.S.A.

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FJPH

CELAZOME MOISTURIZING SPF 30 ACTIVE

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58466-901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	50 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	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:58466-901-04	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
OTC MONOGRAPH FINAL	part352	10/01/2015	

Labeler - Dermazone Solutions, Inc. (136116865)

Establishment

Name	Address	ID/FEI	Business Operations
Deramzone Solutions, Inc.		136 116 865	MANUFACTURE(58466-901)

Revised: 11/2018

Dermazone Solutions, Inc.