

CELAZOME MOISTURIZING SPF 30 ACTIVE- oxybenzone, octinoxate, octisalate, and homosalate cream
Dermazone LLC

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)



celazome[®]
clinical skin care

Moisturizing Sunscreen

Clinical Skin Care with
Lyphazome[®] Technology

SPF 30 ACTIVE
SPORT

WATER RESISTANT
(80 MINUTES)

4 OZ (113 g)

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.

Drug Facts

Active ingredients	Purpose
Benzophenone-3 5.0% Ethylhexyl Methoxycinnamate 7.5% Ethylhexyl Salicylate 5.0% Homosalate 5.0%	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, scititol, dicaprylyl maleate, alcohol, potassium cetyl phosphate, lecithin, cetyl alcohol, dimethicone, tocopheryl acetate, aloe barbadensis leaf juice, carbomer, methylparaben, propylparaben, methacrylamine

FJPH

CELAZOME MOISTURIZING SPF 30 ACTIVE

oxybenzone, octinoxate, octisalate, and homosalate cream

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: 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, UNSPECIFIED (UNII: 92RU3N3Y10)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

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 DRUG	M020	10/01/2015	

Labeler - Dermazone LLC (131639839)

Establishment

Name	Address	ID/FEI	Business Operations
Dermazone LLC		131639839	MANUFACTURE(58466-901) , PACK(58466-901)

Revised: 7/2025

Dermazone LLC