

**SUN CARE FOR FACE- octinoxate avobenzone zinc oxide octocrylene emulsion
Zenith Medicosm SL**

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.

Drug Facts

Active Ingredient

Octinoxate 7.5%

Octocrylene 10%

Avobenzone 3%

Zinc Oxide 24%

Description

SUN CARE CREAM FOR FACE

SPF 25

MEDIUM PROTECTION

UVA - UVB - WATER RESISTANT

Exclusive emulsion with a new protection system against UVA and UVB rays and active ingredients responsible for cell longevity (marine DNA, collagen, sirtuin activators).

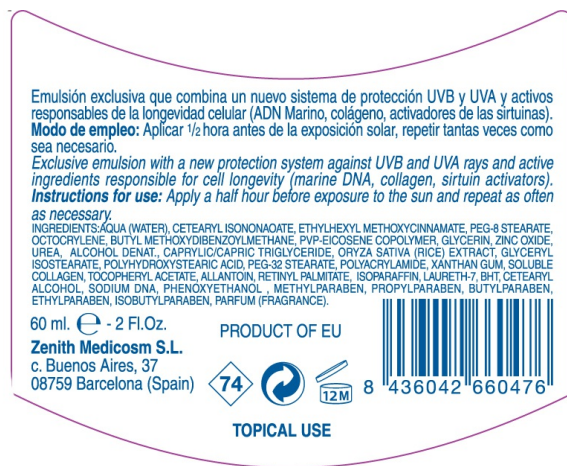
60ml. 2Fl.Oz.

Warning

TOPICAL USE

Instructions for use

Apply half hour before exposure to the sun and repeat as often as necessary.



SUN CARE FOR FACE

octinoxate avobenzene zinc oxide octocrylene emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42248-121
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4.5 mL in 60 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.8 mL in 60 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.4 mL in 60 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	4.5 mL in 60 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM DESOXYCHOLATE (UNII: 436LS6U35Y)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 900 KD) (UNII: B70CUU14M9)	
WATER (UNII: 059QF0K00R)	
TRICAPRYLIN (UNII: 6P92858988)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
C12-14 ISOPARAFFIN (UNII: WP37Z9V66A)	
1-ETHYL-2-PYRROLECARBOXYALDEHYDE (UNII: 51J1CE738Y)	
RICE GERM (UNII: 7N2B70SFEZ)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
LAURETH-7 (UNII: Z95S6G8201)	

XANTHAN GUM (UNII: TTV12P4NEE)
GLYCERIN (UNII: PDC6A3C0OX)
METHYLPARABEN (UNII: A2I8C7H9T)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BUTYLPARABEN (UNII: 3QPII3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
UREA (UNII: 8W8T17847W)
ALCOHOL (UNII: 3K9958V90M)
PEG-32 STEARATE (UNII: 33GX5WQC0M)
ALLANTOIN (UNII: 344S277G0Z)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42248-121-01	60 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/15/2011	

Labeler - Zenith Medicosm SL (464239694)

Registrant - Zenith Medicosm SL (464239694)

Establishment

Name	Address	ID/FEI	Business Operations
Zenith Medicosm SL		464239694	manufacture