

**SUN CARE FOR FACE- octinoxate avobenzone zinc oxide octocrylene cream  
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.*

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**Drug Facts**

**Active Ingredient**

Octinoxate 7.5%

Octocrylene 10%

Avobenzone 3%

Zinc Oxide 24%

**Description**

SUN CARE CREAM FOR FACE

SPF 50

HIGH 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.

**SKINTIMES**  
SUN CARE CREAM FOR FACE

SPF **50** HIGH PROTECTION  
UVA - UVB - WATER RESISTANT

**ZENITH**  
MEDICAL COSMETICS

Crema exclusiva que combina un nuevo sistema de protección UVB y UVA y activos responsables de la longevidad celular (ADN Marino, colágeno, activadores de las sirtuinas).  
**Modo de empleo:** Aplicar 1/2 hora antes de la exposición solar, repetir tantas veces como sea necesario.

Exclusive emulsion with a new protection system against UVB and UVA rays and active ingredients responsible for cell longevity (marine DNA, collagen, sirtuin activators).  
**Instructions for use:** Apply a half hour before exposure to the sun and repeat as often as necessary.

INGREDIENTS: AQUA (WATER), PROPYLENE GLYCOL, OCTOCRYLENE, ETHYLHEXYL METHOXYCINNAMATE, BUTYL METHOXYDIBENZOYL METHANE, ZINC OXIDE, POLYACRYLAMIDE, CAPRYLYL/CAPRIC TRIGLYCERIDE, GLYCERYL ISOSTEARATE, POLYHYDROXYSTEARIC ACID, C-13-14 ISOPARAFFIN, PVP-ECOSENE COPOLYMER, ORYZA SATIVA (RICE) EXTRACT, TOCOPHERYL ACETATE, PANTHENOL, LAURETH-7, XANTHAN GUM, SOLUBLE COLLAGEN, SODIUM DNA, DISODIUM EDTA, RETINYL PALMITATE, PHENOXYETHANOL, METHYLPARABEN, PROPYLPARABEN, BUTYLPARABEN, ETHYLPARABEN, ISOBUTYLPARABEN, PARFUM (FRAGRANCE).

60 ml. e - 2 Fl.Oz.  
**Zenith Medicosm S.L.**  
c. Buenos Aires, 37  
08759 Barcelona (Spain)

PRODUCT OF EU



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TOPICAL USE

## SUN CARE FOR FACE

octinoxate avobenzone zinc oxide octocrylene cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42248-120
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM DESOXYCHOLATE</b> (UNII: 436LS6U35Y)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC10H)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>COLLAGEN, SOLUBLE, FISH SKIN</b> (UNII: 8JC99XGU4W)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 900 KD)</b> (UNII: B70CUU14M9)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>TRICAPRYLIN</b> (UNII: 6P92858988)	
<b>GLYCERYL ISOSTEARATE</b> (UNII: HYE7O27HAO)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>C12-14 ISOPARAFFIN</b> (UNII: WP37Z9V66A)	
<b>1-ETHYL-2-PYRROLECARBOXYALDEHYDE</b> (UNII: 51J1CE738Y)	
<b>RICE GERM</b> (UNII: 7N2B70SFEZ)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>ISOBUTYL PARABEN</b> (UNII: 0QQJ25X58G)	
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>BUTYL PARABEN</b> (UNII: 3QP1I03FV8)	
<b>ETHYL PARABEN</b> (UNII: 14255EXE39)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42248-120-01	60 mL in 1 TUBE		

<b>Marketing Information</b>				
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)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Zenith Medicosm SL		464239694	manufacture