

PRO LASER BODY- octinoxate, titanium dioxide, oxybenzone 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.

Drug Facts

Active Ingredient

Octinoxate 7.5%

Titanium Dioxide 25%

Oxybenzone 6%

Description

PRO LASER BODY EMULSION

SPF 35

Protective body cream formulated with the perfect combination of sunscreens capable of covering a larger area of the solar radiation spectrum. Indicated for use after laser body treatments and surgery, and for skin that has been subjected to aggressive treatments and that needs extreme protection and rapid regeneration

Apply by rubbing into the skin until completely absorbed. Repeat 2 to 3 times a day. Not water resistant.
150ml. 5.1 fl. Oz

Warning

TOPICAL USE

Crema protectora corporal, formulada con una perfecta combinación de filtros solares capaces de cubrir una zona más amplia del espectro de radiación solar.

Indicada en tratamientos corporales laser, post-quirúrgicos y en todas aquellas pieles que hayan sido sometidas a tratamientos agresivos y que necesiten una protección extrema y una regeneración rápida

Modo de empleo: Aplicar masajeando hasta su total absorción. Repetir la operación 2-3 veces al día. No resistente al agua.

Protective body cream formulated with the perfect combination of sunscreens capable of covering a larger area of the solar radiation spectrum.

Indicated for use after laser body treatments and surgery, and for skin that has been subjected to aggressive treatments and that needs extreme protection and rapid regeneration

Instructions for use: Apply by rubbing into the skin until completely absorbed. Repeat 2 to 3 times a day. Not water resistant.

Ingredients: AQUA, ETHYLHEXYL COCOATE, ETHYLHEXYL METHOXYCINNAMATE, GLYCERIN, BENZOPHENONE-3, TITANIUM DIOXIDE, ALUMINA, SODIUM POLYACRYLATE, SODIUM METHYLPARABEN, GLYCERYL STEARATE, PEG-100 STEARATE, CERA ALBA, HYDROLIZED ELASTIN, LECITHIN, SOLUBLE COLLAGEN, METHYLSILANOL HYDROXYPROLINE ASPARTATE, TOCOPHERYL ACETATE, PARFUM, CARBOMER, TRIETHANOLAMINE, PHENOXYETHANOL, ETHYLPARABEN, BUTYLPARABEN, METHYLPARABEN, PROPYLPARABEN, ISOBUTYLPARABEN, IMIDAZOLIDINYL UREA, DISODIUM EDTA.

TOPICAL USE



150 ml.e
5,1 FL.Oz.



Zenith Medicosm S.L.
C.Buenos Aires, 37- 08759
Barcelona (Spain)
PRODUCT OF EU

oceamar

BODY CARE

Pro-Laser Body
Cream

[ZENITH]
MEDICAL COSMETICS

PRO LASER BODY

octinoxate, titanium dioxide, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42248-130
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	11.25 mL in 150 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	37.5 mL in 150 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	9 mL in 150 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
COCONUT ACID (UNII: 40U37V505D)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WHITE WAX (UNII: 7G1J5DA97F)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
HYDROLYZED ELASTIN, BOVINE, ALKALINE (1000 MW) (UNII: ZR28QKN0WT)	
CARBOMER 934 (UNII: Z135WT9208)	
IMIDUREA (UNII: M629807ATL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLPARABEN (UNII: 3QP1I1U3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
(2-CARBETHOXYETHYL)DIETHOXY(METHYL)SILANE (UNII: N28HAC3H5P)	
HYDROXYPROLINE (UNII: RMB44WO89X)	
ASPARTIC ACID (UNII: 30KYC7MIAI)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42248-130-01	150 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2011	

Labeler - Zenith Medicosm SL (464239694)

Registrant - Zenith Medicosm SL (464239694)

Establishment

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

Revised: 5/2012

Zenith Medicosm SL