

PROTECTOR R PLUS- 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

Made with plant squalene, marine collagen and hyaluronic acid, intensive cream with double moisturizing control provides an overall reduction of signs of ageing by progressively activating natural defence mechanisms. It strenghtens the moisture barrier and favours the skin regeneration process. Suitable for use on very dry, dehydrated skin with wrinkles and lack of elasticity.

200ml. 6.8 fl. Oz

Warning

TOPICAL USE

PROFESSIONAL USE

SKINTIMES
Collagen Protect-R Plus

CREAM

PR

[ZENITH]
MEDICAL COSMETICS

Crema protectora y regeneradora con efecto cubriente, indicada en todos los tratamientos en que se requiere un bloqueo total de las radiaciones solares, operaciones quirúrgicas, láser, dermoabrasión, peeling químico, etc. Su formulación exclusiva con **colágeno marino, elastina, hidroxipropilsilano** y una combinación de filtros solares, protege altamente de las radiaciones solares a la vez que regenera la piel de forma rápida.

Modo de empleo: Aplicar sobre piel limpia, masajeando hasta su absorción. Repetir la operación dos veces al día.

Protective, regenerating cream with sun-block effect. Indicated for all situations requiring full sun block, such as after surgery, laser treatments, dermabrasion, chemical peels, etc. Its exclusive formula with **marine collagen, elastin, hydroxypropylsilane** and solar filters provides full protection from the sun and quickly regenerates the skin.

Instructions for use: Apply twice a day on clean skin and rub in until completely absorbed.

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, METYLPARABEN, PROPYLPARABEN, ISOBUTYLPARABEN, IMIDAZOLIDINYL UREA, DISODIUM EDTA.



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48



TOPICAL USE
PROFESSIONAL ONLY



Zenith Medicosm S.L. C. Buenos Aires, 37.
08759 Barcelona (Spain)

200ml. e PRODUCT OF EU 6,8 FL.Oz.

PROTECTOR R PLUS

octinoxate, titanium dioxide, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42248-124
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	15 mL in 200 mL

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	50 mL in 200 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	12 mL in 200 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
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: 30KYC7MIAD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42248-124-01	200 mL in 1 TUBE		

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: 2/2012

Zenith Medicosm SL