

**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.

50ml. 1.7 fl. Oz

**Warning**

*TOPICAL USE*



## PROTECTOR R PLUS

octinoxate, titanium dioxide, oxybenzone cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:42248-127

## Route of Administration

TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 mL in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	12.5 mL in 50 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 mL in 50 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: 0QJ25X58G)	
HYDROLYZED ELASTIN, BOVINE, ALKALINE (1000 MW) (UNII: ZR28QKN0WT)	
CARBOMER 934 (UNII: Z135WT9208)	
IMIDUREA (UNII: M629807ATL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A218C7HI9T)	
COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLPARABEN (UNII: 3QP1IU3FV8)	
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:42248-127-02	1 in 1 BOX		
1		50 mL in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

**Labeler** - Zenith Medicosm SL (464239694)

**Registrant** - Zenith Medicosm SL (464239694)

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

Revised: 2/2012

Zenith Medicosm SL