

HYALURONIC FILLER SERUM- octinoxate 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%

Description

Serum with two forms of hyaluronic acid, peptide fillers and marine collagen that generates an instantaneous effect by restoring skin volume and visibly reducing wrinkles. Indicated for rough skin with deep wrinkles.

30 ml. 1 FL. Oz

Warning

TOPICAL USE



HYALURONIC FILLER SERUM

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42248-125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.25 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOBUTYLPARABEN (UNII: 0QJ25X58G)	
ACRYLAMIDE (UNII: 20R035KLCI)	
SODIUM ACRYLATE (UNII: 7C98FKB43H)	
DIMETHICONOL (250000 MW) (UNII: RKI3S914RT)	
PANTHENOL (UNII: WV9CM0O67Z)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HYALURONIC ACID (UNII: S270N0TRQY)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42248-125-02	1 in 1 BOX		
1		30 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph 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