

ESIKA PRO HYDRA SMART HYDRO-NUTRITIVE FOUNDATION SPF 15- octinoxate, zinc oxide cream

Ventura Corporation Limited

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.

Esika Pro Hydra Smart Hydro-nutritive foundation SPF 15

Active Ingredients Purpose

Avobezone 1.80% Sunscreen

Octocrylene 4.5% Sunscreen

Octisalate 4.5% Sunscreen

Uses

- Helps prevent sunburn

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help sunburn, **not** skin cancer or early skin aging.

For external use only.

When using this product keep out of eyes. Rinse with water to remove

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months of age: Ask a doctor.

Inactive ingredients:

Dimethicone, water, PEG-10 dimethicone, isododecane, glycerin, polymethylsilsesquioxane, peg/ppg-18/18 dimethicone, hdi/trimethylol hexyllactone crosspolymer, hydroxyethyl urea, polymethylsilsesquioxane/trimethylsiloxysilicate, polysilicone-11, Zea Mays (corn) starch, sodium pca, dimethicone/vinyl dimethicone crosspolymer, silica, phenoxyethanol, sorbitan sesquioleate, tocopheryl acetate, methylpropanediol, caprylyl glycol, chlorphenesin, disteardimonium hectorite, silanediol salicylate, pisum sativum (pea) extract extract, tromethamine, peg-8 caprylic/capric glycerides, octyldodeceth-25, sodium hyaluronate, propylene glycol, decylene.

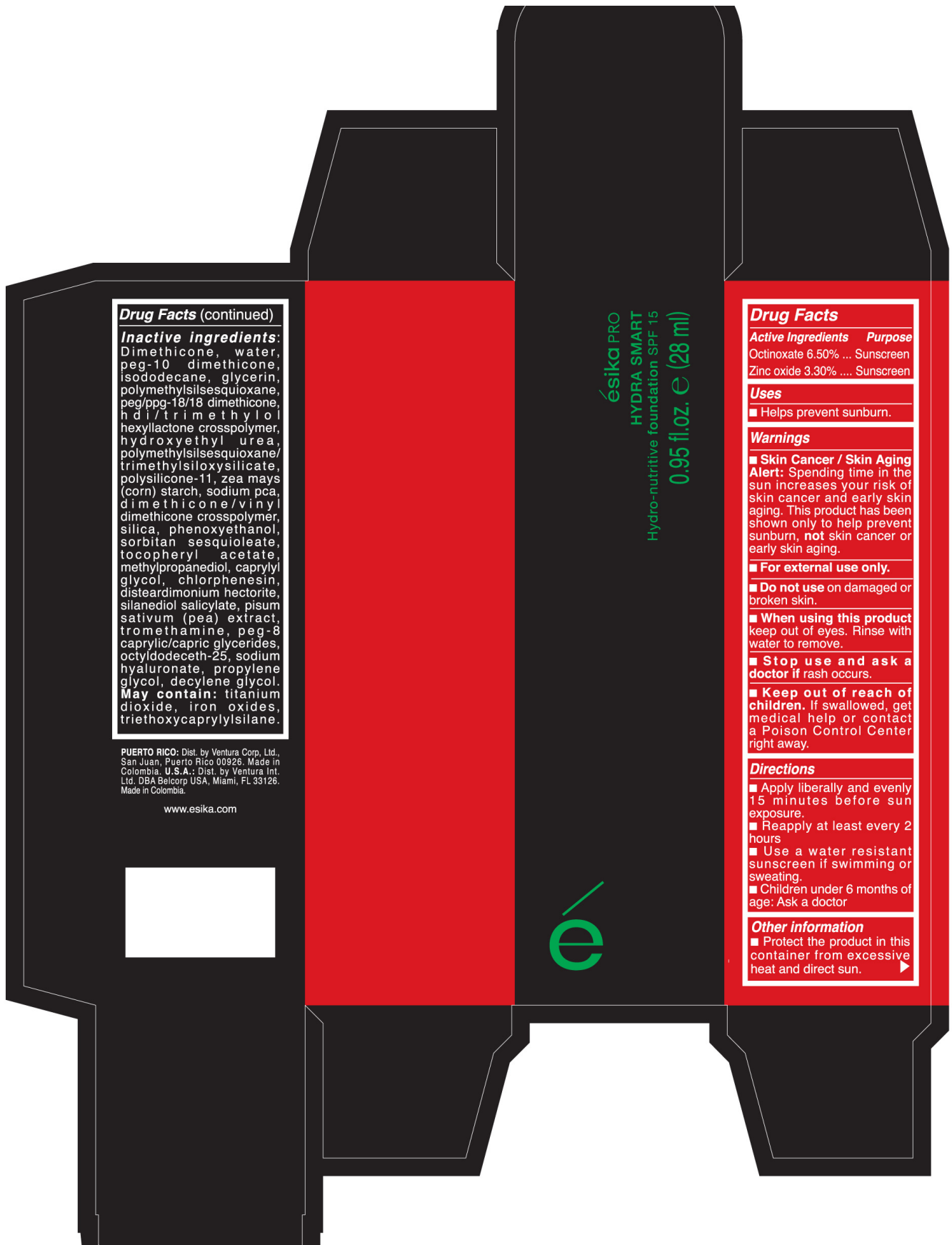
May contain titanium, iron oxides, triethoxycaprylylsilane

Esika Pro

HYDRA SMART

hydra-nutritive foundation SPF 15

0.95 fl oz e (28 ml)



Drug Facts (continued)

Inactive ingredients:
 Dimethicone, water, peg-10 dimethicone, isododecane, glycerin, polymethylsilsesquioxane, peg/ppg-18/18 dimethicone, hdi/trimethylol hexyllactone crosspolymer, hydroxyethyl urea, polymethylsilsesquioxane/trimethylsiloxysilicate, polysilicone-11, zeamays (corn) starch, sodium pca, dimethicone/vinyl dimethicone crosspolymer, silica, phenoxyethanol, sorbitan sesquioleate, tocopheryl acetate, methylpropanediol, caprylyl glycol, chlorphenesin, disteardimonium hectorite, silanediol salicylate, pisum sativum (pea) extract, tromethamine, peg-8 caprylic/capric glycerides, octyldodeceth-25, sodium hyaluronate, propylene glycol, decylene glycol. **May contain:** titanium dioxide, iron oxides, triethoxycaprylylsilane.

PUERTO RICO: Dist. by Ventura Corp. Ltd., San Juan, Puerto Rico 00926. Made in Colombia. U.S.A.: Dist. by Ventura Int. Ltd. DBA Belcorp USA, Miami, FL 33126. Made in Colombia.

www.esika.com

esika PRO
 HYDRA SMART
 Hydro-nutritive foundation SPF 15
 0.95 fl.oz. e (28 ml)

Drug Facts

Active Ingredients	Purpose
Octinoxate 6.50% ...	Sunscreen
Zinc oxide 3.30% ...	Sunscreen

Uses

- Helps prevent sunburn.

Warnings

- **Skin Cancer / Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.
- **For external use only.**
- **Do not use** on damaged or broken skin.
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

Other information

- Protect the product in this container from excessive heat and direct sun. ▶

ESIKA PRO HYDRA SMART HYDRO-NUTRITIVE FOUNDATION SPF 15

octinoxate, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0136
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.065 g in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.33 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
PEA (UNII: W4X7H8GYFM)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ISODODECANE (UNII: A8289P68Y2)	
HYDROXYETHYL UREA (UNII: MBQ7DDQ7AR)	
STARCH, CORN (UNII: O8232NY3SJ)	
CAPRYLOCAPROYL POLYOXYLGLYCERIDES 8 (UNII: 00BT03FSO2)	
TROMETHAMINE (UNII: 023C2WHX2V)	
OCTYLDODECETH-25 (UNII: F8934HEL3M)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DECYLENE GLYCOL (UNII: S57M60MI88)	
DIMETHICONE 100 (UNII: RO266O364U)	
WATER (UNII: 059QF0K00R)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43596-0136-1	28 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/10/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/10/2019	

Labeler - Ventura Corporation Limited (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	manufacture(43596-0136)

Revised: 12/2019

Ventura Corporation Limited