

**ESIKA PROTECTOR AGAINST SOLAR RAYS FOR CHILDREN, FACE AND BODY SPF 50-  
ensulizole, octinoxate, octisalate, octocrylene, oxybenzone, and titanium dioxide lotion  
Ventura Corporation LTD**

*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 PROTECTOR AGAINST SOLAR RAYS FOR CHILDREN, FACE AND BODY SPF 50**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Ensulizole (3%)	Sunscreen
Octinoxate (7.5%)	Sunscreen
Octisalate (5%)	Sunscreen
Octocrylene (7%)	Sunscreen
Oxybenzone (6%)	Sunscreen
Titanium Dioxide (4.7%)	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.

**Inactive ingredients**

Aqua (water), arginine, butylparaben, cetareth-20, cetearyl alcohol, cyclohexasiloxane, cyclopentasiloxane, dicaprylyl carbonate, dimethicone, disodium lauriminodipropionate tocopheryl phosphates, ethylparaben, glyceryl stearate, isobutylparaben, methicone, methyl methacrylate crosspolymer, methylparaben, parfum (fragrance), phenethyl benzoate, phenoxyethanol, potassium cetyl phosphate, propylparaben, silica, sorbitan stearate, trimethylsiloxysilicate, vp/eicosene copolymer, xanthan gum.

**PR:** Distributed by Ventura Corporation, Ltd. San Juan, Puerto Rico 00926.

**PRINCIPAL DISPLAY PANEL - 80 ml Bottle Label**

**SPF**

**50**

Perfect

**sun**

**Kids**

Sunscreen

protector against solar  
rays for children, face and  
body SPF 50

ēsika

80 ml e (2.7 fl.oz.)



**Drug Facts**

**Active Ingredients .... Purpose**

Ensulizole (3.0%)	.....Sunscreen
Octinoxate (7.5%)	.....Sunscreen
Octisalate (5.0%)	.....Sunscreen
Octocrylene (7.0%)	.....Sunscreen
Oxybenzone (6.0%)	.....Sunscreen
Titanium Dioxide (4.7%)	.....Sunscreen

**Uses**

- Helps prevent sunburn.

**Warnings**

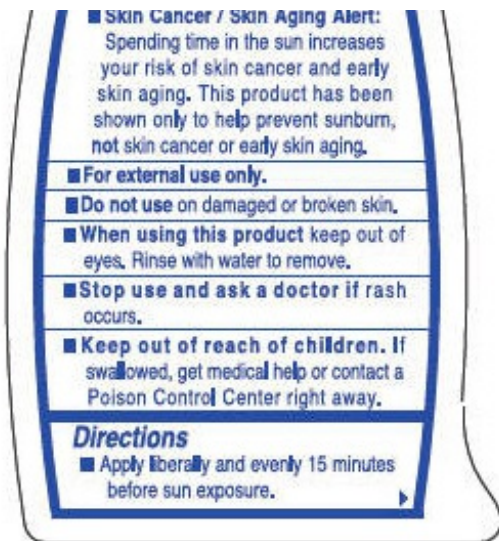
**Drug Facts (continued)**

- 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.

**Inactive ingredients**



## ESIKA PROTECTOR AGAINST SOLAR RAYS FOR CHILDREN, FACE AND BODY SPF 50

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### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-224
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ensulizole (UNII: 9 YQ9 D11W42) (Ensulizole - UNII:9 YQ9 D11W42)	Ensulizole	0.03 g in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 mL
Octisalate (UNII: 4X49 Y0596 W) (Octisalate - UNII:4X49 Y0596 W)	Octisalate	0.05 g in 1 mL
Octocrylene (UNII: 5A68 WGF6 WM) (Octocrylene - UNII:5A68 WGF6 WM)	Octocrylene	0.07 g in 1 mL
Oxybenzone (UNII: 95OOS7VE0 Y) (Oxybenzone - UNII:95OOS7VE0 Y)	Oxybenzone	0.06 g in 1 mL
Titanium Dioxide (UNII: 15FIX9 V2JP) (Titanium Dioxide - UNII:15FIX9 V2JP)	Titanium Dioxide	0.046 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ARGININE (UNII: 94ZLA3W45F)	
BUTYLPARABEN (UNII: 3QP11U3FV8)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
ETHYLPARABEN (UNII: 14255EXE39)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
METHYL PARABEN (UNII: A2I8C7H9T)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-224-01	80 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/16/2013	

**Labeler** - Ventura Corporation LTD (602751344)

### Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-224)

Revised: 12/2013

Ventura Corporation LTD