

**ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT
SPF 25- octinoxate and zinc oxide lipstick
Ventura International 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.

Ésika Pro HIDRACOLOR 3 in 1 Moisturizing Lipstick, Color and Perfecting Effect SPF 25

Drug Facts

Active Ingredients	Purpose
OCTINOXATE 7.5%	Sunscreen
ZINC OXIDE 3.92%	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

dipentaerythrityl hexacaprylate/hexacaprate, tridecyl trimellitate, isononyl isononanoate, ozokerite, water, polyglyceryl-3 diisostearate, tridecyl stearate, polyethylene, copernicia cerifera (carnauba) wax, glycerin, neopentyl glycol dicaprylate/dicaprate, butyrospermum parkii (shea) butter, ptfе, sodium starch octenylsuccinate, tocopheryl acetate, caprylic/capric triglyceride, phenoxyethanol, cocos nucifera (coconut) oil, aloe barbadensis leaf extract, fragrance, ceramide 3, caprylyl glycol, chlorphenesin,

dimethicone, triethoxycaprylylsilane, glycine soja (soybean) oil, limonium gerberi extract, trimethylsiloxysilicate, tocopherol, magnesium chloride, potassium chloride, silica, sodium chloride, crambe maritima extract, alpha-isomethyl ionone, d-limonene, linalool, amyl cinnamal, citronellol.

May Contain: red 30 lake, titanium dioxide, iron oxides, mica, red 27 lake, yellow 5 lake, red 7 lake, red 21 lake, talc, blue 1 lake, carmine.

Dist. by Ventura Int.

Ltd. DBA Belcorp USA, Miami, FL 33126.

PRINCIPAL DISPLAY PANEL - 4 g Tube Box

ésika

PRO

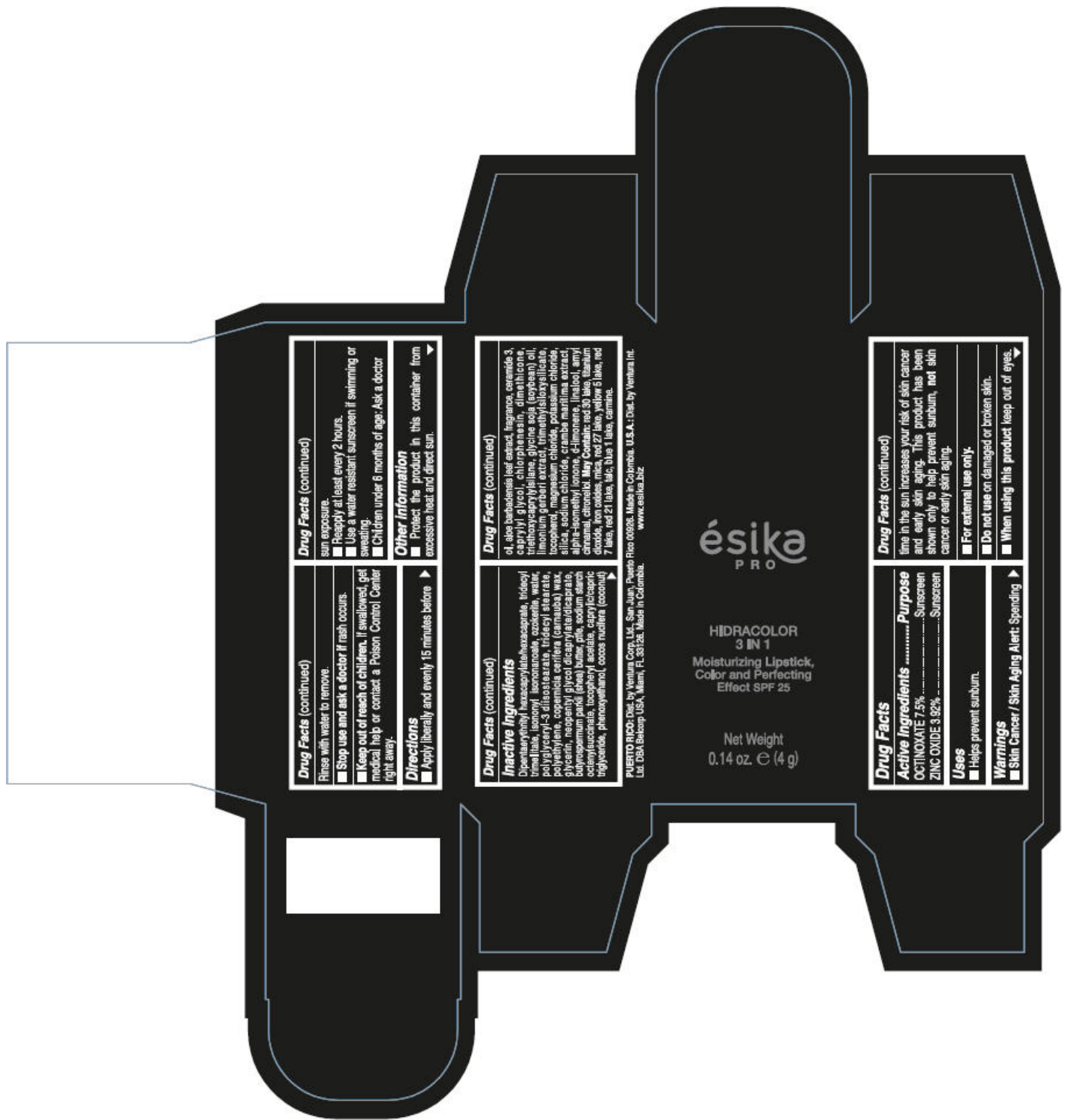
HIDRACOLOR

3 IN 1

**Moisturizing Lipstick,
Color and Perfecting
Effect SPF 25**

Net Weight

0.14 oz. e (4 g)



ESIKA PRO HIDRACOLOR 3 IN 1 MOISTURIZING, COLOR AND PERFECTING EFFECT SPF 25
 octinoxate and zinc oxide lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.075 g in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.0392 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
dipentaerythrityl hexacaprylate/hexacaprate (UNII: 554N82UWVW)	
tridecyl trimellitate (UNII: FY36J270ES)	
isononyl isononanoate (UNII: S4V5BS6GCX)	
ceresin (UNII: Q1LS2UJO3A)	
water (UNII: 059QF0KO0R)	
polyglyceryl-3 diisostearate (UNII: 46P231IQV8)	
tridecyl stearate (UNII: A8OE252M6L)	
high density polyethylene (UNII: UG00KM4WR7)	
carnauba wax (UNII: R12CBM0EIZ)	
glycerin (UNII: PDC6A3C0OX)	
neopentyl glycol dicaprylate/dicaprate (UNII: VLW429K27K)	
shea butter (UNII: K49155WL9Y)	
polytetrafluoroethylene (UNII: E1NC1JVS3O)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
medium-chain triglycerides (UNII: C9H2L21V7U)	
phenoxyethanol (UNII: HIE492ZZ3T)	
coconut oil (UNII: Q9L0O73W7L)	
aloe vera leaf (UNII: ZY81Z83H0X)	
ceramide np (UNII: 4370DF050B)	
caprylyl glycol (UNII: 00YIU5438U)	
chlorphenesin (UNII: I670DAL4SZ)	
dimethicone (UNII: 92RU3N3Y1O)	
triethoxycaprylylsilane (UNII: LDC331P08E)	
soybean oil (UNII: 241ATL177A)	
tocopherol (UNII: R0ZB2556P8)	
magnesium chloride (UNII: 02F3473H9O)	
potassium chloride (UNII: 660YQ98I10)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium chloride (UNII: 451W47IQ8X)	
isomethyl-.alpha.-ionone (UNII: 9XP4LC555B)	
limonene, (+)- (UNII: GFD7C86Q1W)	
linalool, (+/-)- (UNII: D81QY6I88E)	
.alpha.-amylcinnamaldehyde (UNII: WC51CA3418)	
.beta.-citronellol, (r)- (UNII: P01OUT964K)	
d&c red no. 30 (UNII: 2S42T2808B)	
aluminum oxide (UNII: LM26O6933)	
titanium dioxide (UNII: 15FIX9V2JP)	
ferric oxide red (UNII: 1K09F3G675)	
mica (UNII: V8A1AW0880)	
d&c red no. 27 (UNII: 2LRS185U6K)	
fd&c yellow no. 5 (UNII: I753WB2F1M)	
d&c red no. 7 (UNII: ECW0LZ41X8)	

d&c red no. 21 (UNII: 08744Z6JNY)	
talc (UNII: 7SEV7J4R1U)	
fd&c blue no. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-112-01	1 in 1 BOX	04/19/2017	
1		4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	04/19/2017	

Labeler - Ventura International LTD (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-112)

Revised: 4/2017

Ventura International LTD