

**FOUNDATION SUNSCREEN FACE STICK BROAD SPECTRUM SPF 38 KONA GOLD-titanium dioxide stick**

**Eai-jr 286, Inc**

*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.*

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**Foundation Sunscreen Face Stick Broad Spectrum SPF 38 Kona Gold**

<i>Active ingredients</i>	<i>Purpose</i>
Titanium Dioxide 23%	Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin aging caused by the sun

**Keep out of reach of children.** If swallowed, get medical help or call a Poison Control Center right away.

**Stop use and ask a doctor** if rash or irritation develops and lasts.

**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

Directions

- **apply liberally** and evenly 15 minutes before sun exposure
- apply to all skin exposed to sun
- use a water resistant sunscreen if swimming or sweating
- reapply: after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **Sun Protection Measures.**
- spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum value 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m.-2p.m.
- wear long-sleeve shirts, pants, hats and sunglasses
- children under 6 months of age: ask a doctor

Hexyldecyl Isostearate, Aluminum Hydroxide, Mica, Iron Oxides, Stearic Acid, Paraffin, Ozokerite, Synthetic Wax, Ethylene/propylene copolymer, Polyglyceryl-2 Oleate, Tocopherol, fragrance, Stearyl Glycyrhethinate

Vertra Premium Suncare

SPF 38

Premium Mineral Based

Foundation Sunscreen Face Stick

Reef Safe

Broad Spectrum SPF 38

Water Resistant (80 minutes)

Color: Kona Gold

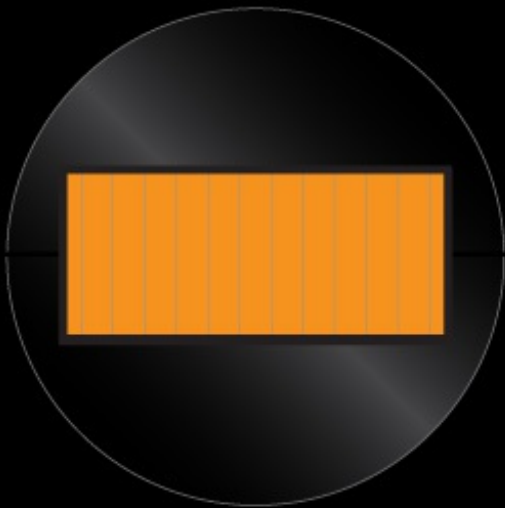
11g NET Wt. 0.39 oz



MENTAL RESISTANCE  
**artrea**  
SHANE DORIAN

**SPF38**

SUNSCREEN FACE STICK  
BROAD SPECTRUM SPF 38  
WATER RESISTANT (80 MINUTES)  
11g NET WT. 0.39 OZ.



**Active Ingredients**  
TITANIUM DIOXIDE 23%

**Purpose:** SUNSCREEN

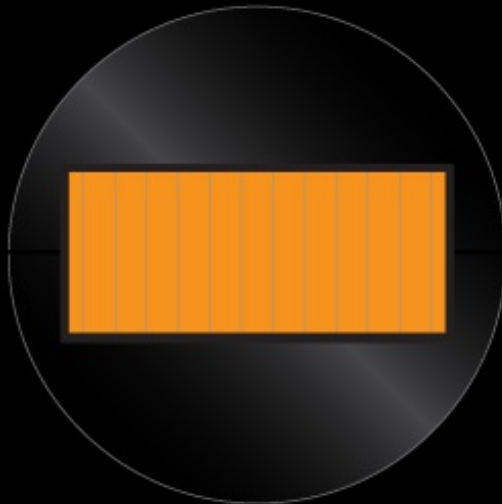
**Warnings**

For external use only • Do not use on damaged or broken skin • When using this product keep out of eyes • Keep out of reach of children

**Directions**

• Apply liberally 15 minutes before sun exposure • Reapply every 80 minutes of swimming or sweating • Do not use on children under 6 months of age

Vertra, EAI-JR286, Inc.  
Torrance, CA 90502  
Made in Japan



**FOUNDATION SUNSCREEN FACE STICK BROAD SPECTRUM SPF 38 KONA GOLD**

titanium dioxide stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71014-024
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	23 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
HEXYLDECYL ISOSTEARATE (UNII: 3V20TC06U5)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MICA (UNII: V8A1AW0880)	
CERESIN (UNII: Q1LS2UJO3A)	
PARAFFIN (UNII: I9O0E3H2ZE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71014-024-02	1 in 1 BOX	04/02/2018	
1	NDC:71014-024-01	11 g in 1 CYLINDER; 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	04/02/2018	

**Labeler** - Eai-jr 286, Inc (827896718)

### Establishment

Name	Address	ID/FEI	Business Operations
Toshiki Pigment Company Limited		716140285	manufacture(71014-024)