

**VERTRA S DORIAN KONA GOLD SIGNATURE FACE STICK SPF 38- titanium dioxide stick**

**Toshiki Pigment Co., 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.*

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**Vertra S Dorian Kona Gold Signature Face Stick SPF 38**

**Active Ingredients Purpose**

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
- Higher SPF gives more sunburn protection.
- Retains SPF after 80 minutes activity in the water, sweating, or perspiring
- Provides high protection against 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 or irritation develops and lasts

**Warnings**

Do not use:

- On damaged or broken skin

**When using this product:**

- Keep out of eyes. Rinse with water to remove.

**For external use only**

**Directions**

Apply liberally and generously 15 minutes before sun exposure and at least every 2 hours and 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 SPF value of 15 or higher and other sun protection measures including:

- limit your time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months of age: ask a doctor

Reapply:

After 80 minutes of swimming or sweating

Immediately after towel drying

At least every 2 hours

### Inactive Ingredients

Hexyldecyl Isostearate, Aluminum Hydroxide, Mica, Iron Oxides, Stearic Acid, Paraffin, Ozokerite, Synthetic Wax, Ethylene/Propylene Copolymer, Polyglyceryl-2 Oleate, Tocopherol, Stearyl Glycyrhettinate

Kona Gold

vertra

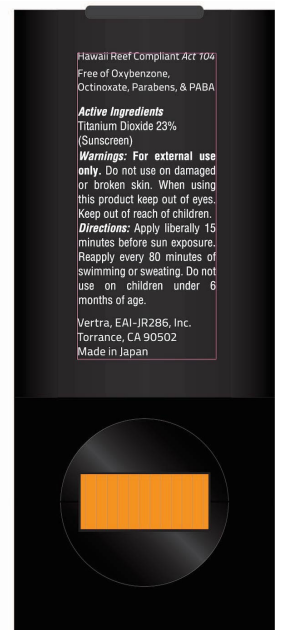
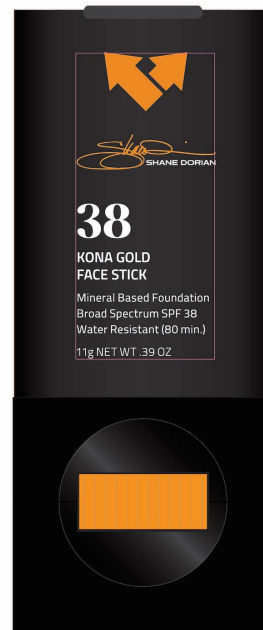
38

Mineral Based Foundation

Broad Spectrum SPF 38

Water Resistant (80 minutes)

11g NET WT. 0.39 OZ



**KONA GOLD  
FACE STICK**  
Medium tan with  
warm undertones

# VERTRA S DORIAN KONA GOLD SIGNATURE FACE STICK SPF 38 titanium dioxide stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:66990-1021
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MICA</b> (UNII: V8A1AW0880)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>SYNTHETIC WAX (1200 MW)</b> (UNII: Q3Z4BCH099)	
<b>POLYGLYCERYL-2 OLEATE</b> (UNII: 5759J47SAM)	
<b>HEXYLDECYL ISOSTEARATE</b> (UNII: 3V20TC06U5)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>STEARYL GLYCYRRHETINATE</b> (UNII: 3YYE6VJS0P)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:66990-1021-1	11 g in 1 CARTON; Type 0: Not a Combination Product	12/18/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	M020	12/18/2020	

**Labeler** - Toshiki Pigment Co., Ltd. (716140285)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Toshiki Pigment Co., Ltd.		716140285	manufacture(66990-1021)

