

**VERTRA EHUKAI BEIGE 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.

Vertra Ehukai Beige 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 Glycyrhethinate

Vertra

38

Ehukai Beige Face Stick

Mineral Based Foundation

Broad Spectrum SPF 38

Water Resistant (80 minutes)

11g NET WT. 0.39 OZ



VERTRA EHUKAI BEIGE FACE STICK SPF 38
titanium dioxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66990-1020
Route of Administration	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
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MICA (UNII: V8A1AW0880)	
PARAFFIN (UNII: I9O0E3H2ZE)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
HEXYLDECYL ISOSTEARATE (UNII: 3V20TC06U5)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
POLYGLYCERYL-2 OLEATE (UNII: 5759J47SAM)	
CERESIN (UNII: Q1LS2UJO3A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66990-1020-1	11 g in 1 BOTTLE; Type 0: Not a Combination Product	12/18/2020	

Marketing Information

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

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

Name	Address	ID/FEI	Business Operations
Toshiki Pigment Co., Ltd.		716140285	manufacture(66990-1020)