

**TRANSLUCENT BROAD SPECTRUM FOUNDATION SPF 50 VERTRA- padimate o, titanium dioxide stick**

**Eai-Jr286, 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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**Vertra Elemental Resistance Broad Spectrum Foundation Face Screen SPF 50 - Translucent**

| <b>Active Ingredients</b> | <b>Purpose</b> |
|---------------------------|----------------|
|---------------------------|----------------|

|               |           |
|---------------|-----------|
| Padamite O 7% | Sunscreen |
|---------------|-----------|

|                      |  |
|----------------------|--|
| Titanium Dioxide 17% |  |
|----------------------|--|

**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 Poison Control Center right away.

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

**Warnings**

**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 SPF value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. - 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
  - children under 6 months of age: ask a doctor

Hexyldecyl Isosterate, Mica, Synthetic wax, Paraffin, Ozokerite, Polyglyceryl-2 Oleate, Aluminum Hydroxide, Stearic Acid, Ethylene/Propylene Copolymer, Tocopheryl, Fragrance, Iron Oxides

Vertra Elemental Resistance

Foundation

Sunscreen Face Stick

Broad Spectrum SPF 50+

Water Resistant (80 minutes)

Color: Translucent

10.5g NET WT. .37 oz.



**vertra**  
PREMIUMSUNSCARE

**Drug Facts**

**Active Ingredients**

PADIMATE O 7%  
TITANIUM DIOXIDE 17%

**Purpose**

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.

**Warnings**

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 or irritation develops and lasts.

**For external use only**

**Keep out of reach of children:**

- If product is swallowed, get medical help or contact a Poison Control Center right away.

Distributed by: Vertra, EAI-JR286, Inc.  
Torrance, CA 90502  
Made in Japan  
Questions or comments:  
hello@vertra.com  
www.vertra.com

**Drug Facts cont.**

**Directions**

- Apply liberally and generously 15 minutes before sun exposure and at least every 2 hours.
- Children under 6 months of age: ask a doctor.
- **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
  - Reapply:
    - After 80 minutes of swimming or sweating
    - Immediately after towel drying
    - At least every 2 hours

**Other Information**

- Protect this product in this container from excessive heat and direct sun

**Inactive Ingredients**

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

**50+**

FOUNDATION  
SUNSCREEN FACE STICK  
BROAD SPECTRUM SPF 50+  
COLOR: TRANSLUCENT



**vertra**  
PREMIUMSUNSCARE

SPF  
**50+**

PREMIUM  
MINERAL BASED  
FOUNDATION SUNSCREEN  
FACE STICK

**ReefSafe**

BROAD SPECTRUM SPF 50+  
WATER RESISTANT (80 MINUTES)  
COLOR: TRANSLUCENT  
10.5g NET WT. 0.37 OZ.

**vertra**  
PREMIUMSUNSCARE

Lightweight, SPF 50, foundation based sunscreen for the face. Optimum Broad Spectrum protection against skin damaging UVA rays and skin burning UVB rays. This Translucent formula glides on smoothly and blends evenly into the skin providing superior sun protection, without sacrificing that natural look. Designed, formulated and manufactured to the highest sunscreen and cosmetic industry standards.

- Oxybenzone Free
- Octinoxate Free
- Reef Safe
- Paraben Free
- Water Resistant (80 Minutes)
- Smooth, non-greasy application



Vertra Elemental Resistance is proud to be the Official Suncare provider for the Hawaiian Lifeguard Association



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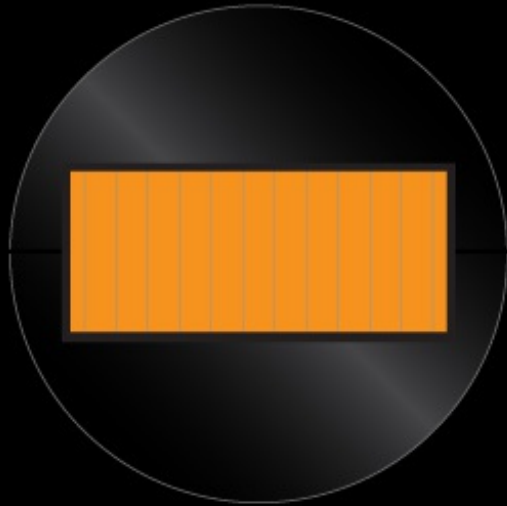
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ENTAL RESISTANCE  
**artura**

**SPF50+**

SUNSCREEN FACE STICK  
BROAD SPECTRUM SPF 50+  
WATER RESISTANT (80 MINUTES)  
10.5g NET WT. 0.37 OZ.



***Active Ingredients***

PADIMATE O 7%

TITANIUM DIOXIDE 17%

TITANIUM DIOXIDE 17.7%

**Purpose:** SUNSCREEN

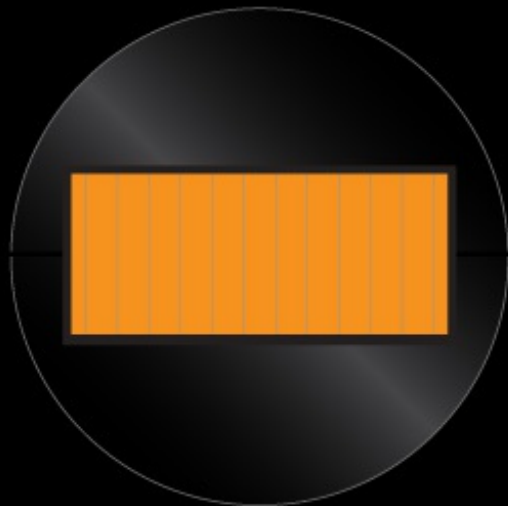
**Warnings**

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



**TRANSLUCENT BROAD SPECTRUM FOUNDATION SPF 50 VERTRA**

padimate o, titanium dioxide stick

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:71014-005

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength         |
|--|-------------------|------------------|
| PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)             | PADIMATE O        | 7 g in 100 g     |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 17.45 g in 100 g |

### Inactive Ingredients

| Ingredient Name                            | Strength |
|--|----------|
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)      |          |
| HEXYLDECYL ISOSTEARATE (UNII: 3V20TC06U5)  |          |
| MICA (UNII: V8A1AW0880)                    |          |
| CERESIN (UNII: Q1LS2UJO3A)                 |          |
| PARAFFIN (UNII: I9O0E3H2ZE)                |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)            |          |
| SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099) |          |
| TOCOPHEROL (UNII: R0ZB2556P8)              |          |

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71014-005-02 | 1 in 1 BOX  | 10/07/2016           |                    |
| 1 | NDC:71014-005-01 | 10.5 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                                  | 10/07/2016           |                    |

**Labeler** - Eai-Jr286, Inc. (827896718)

**Registrant** - Eai-Jr286, Inc. (827896718)

### Establishment

| Name                      | Address | ID/FEI    | Business Operations    |
|---------------------------|---------|-----------|------------------------|
| Toshiki Pigment Co., ltd. |         | 716140285 | manufacture(71014-005) |