

**SUNSCREEN SPF 30- zinc oxide lotion**  
**ERBAVIVA 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.*

-----

**SUNSCREEN**

Active ingredient  
ZINC OXIDE 20%

**PURPOSE**

**SUNSCREEN**

- HELPS PREVENT SUNBURN

**WARNINGS**

- FOR EXTERNAL USE ONLY
- DO NOT USE ON DAMAGED OR BROKEN SKIN.
- KEEP OUT OF EYES. RINSE WITH WATER TO REMOVE.
- AND ASK A DOCTOR IF RASH OCCURS.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- apply liberally 15 minutes before sun exposure.
- use a water resistant sunscreen if swimming or sweating
- reapply 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 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

Inactive ingredients: \*Aloe barbadensis leaf juice, \*anthemis nobilis (chamomile) flower oil, caprylic/capric triglycerides, \*helianthus annuus (sunflower) seed oil, hydrogenated methyl abietate, \*lavandula angustifolia (lavender) flower oil, magnesium sulfate, \*olea europaea (olive) fruit oil, polyaminopropyl biguanide, polyglycerol-10 laurate, ricinus communis (castor) seed oil, \*simmondsia chinensis (jojoba) seed oil, sorbitan stearate, tocopherol, water.

**OTHER INFORMATION**

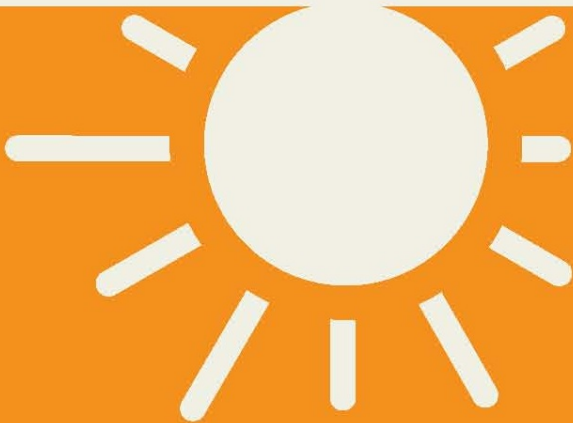
- PROTECT THE PRODUCT IN THIS CONTAINER FROM EXCESSIVE HEAT AND DIRECT SUN.

**ERBAORGANICS**

SPF30  
BROAD SPECTRUM SUNSCREEN

Completely natural water resistant (80 minutes) sunscreen for children and adults.

3/16" Bleed for overlap



**erbaorganics**

**SPF 30**  
broad spectrum sunscreen  
*crème solaire*

Completely natural water resistant (80 minutes) sunscreen for children and adults.

2.5 oz. / 75 g

**Drug Facts**

Active ingredient	Purpose
Zinc Oxide 20%	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

**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.

**Stop use and ask a doctor** if rash occurs

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

**Directions**

- apply liberally 15 minutes before sun exposure.
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: 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 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


**Inactive ingredients** \*Aloe barbadensis leaf juice, \*anthesis nobilis (chamomile) flower oil, caprylic/capric triglycerides, \*helianthus annuus (sunflower) seed oil, hydrogenated methyl abietate, \*lavandula angustifolia (lavender) flower oil, magnesium sulfate, \*olea europaea (olive) fruit oil, polyaminopropyl biguanide, polyglycerol-10 laurate, ricinus communis (castor) seed oil, \*simmondsia chinensis (jojoba) seed oil, sorbitan stearate, tocopherol, water.

**Other information**

- protect this product from excessive heat and direct sun

\*denotes certified organic ingredient.  
\*\*denotes component of certified organic ingredient.

Made in USA  
Los Angeles, CA (877) 336-8080  
London, UK +44 (0) 1753 680980  
www.erbaorganics.com



**FPO**  
BARCODE#: 09967632

## SUNSCREEN SPF 30

zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:43239-101
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430 YW9)	

CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
POLYAMINOPROPYL BIGUANIDE (UNII: 322U039GMF)	
POLYGLYCERYL-10 OLEATE (UNII: 55C81W76DH)	
CASTOR OIL (UNII: D5340Y2I9G)	
JOJOBA OIL (UNII: 724GKU717M)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0K00R)	
GLYCERYL ABIETATE (UNII: 2F22LY70Q1)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43239-101-13	75 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/18/2012	

**Labeler** - ERBAVIVA INC. (006459540)

**Registrant** - ERBAVIVA INC. (006459540)