

**THERMASUN ZINXATION MINERAL ZINC FACIAL SUNSCREEN - ACNE PRONE SKIN SPF-50- zinc oxide lotion**  
**ASTIVITA LIMITED**

*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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**THERMASUN ZINXATION MINERAL ZINC FACIAL SUNSCREEN - ACNE-PRONE SKIN - SPF-50**

**ACTIVE INGREDIENT**

ZINC OXIDE (25.0% W/W)

**PURPOSE**

SUNSCREEN

**USES**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreased 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 doctor if rash occurs

**DIRECTIONS**

- apply liberally and evenly 20 minutes before sun exposure
- reapply: After 40 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-sleeved shirts, pants, hats, and sunglasses
- children under 6 months of age: ask a doctor

**INACTIVE INGREDIENTS**

Aqua, coco-caprylate/caprate, glycerine, coconut alkane, simmondsia chinensis (jojoba) seed oil, polyglyceryl-3-polyricinoleate, cera alba (beeswax), isostearic acid, polyhydroxystearic acid, maltodextrin, matricaria chamomilla (German chamomile extract), phenylpropanol, propanediol, caprylyl glycol, tocopherol (vitamin e), ethylhexylglycerin, cetyl phosphate, sodium chloride, disodium EDTA

## **QUESTIONS?**

[contact@thermasunskin.com](mailto:contact@thermasunskin.com)

# ThermaSun<sup>®</sup>

## ZINXATION

### SPF 50

*Broad Spectrum Protection SPF 50*

### MINERAL ZINC FACIAL SUNSCREEN

*suitable for acne prone  
& sensitive skin*

- ◆ Organic Zinc Oxide
- ◆ High Purity Vitamin E
- ◆ Water Resistant 40 Minutes
- ◆ High UVA/UBA Protection
- ◆ Formulated with Matricaria Chamomilla



*Formulated in Australia*

3.4 fl. oz / 100 ml cream

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# ThermaSun<sup>®</sup>

## ZINXATION

### Drug Facts

Active Ingredient	Purpose
Zinc Oxide (25.0% w/w)	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 doctor** if rash occurs

### Directions

- **apply liberally** and evenly 20 minutes before sun exposure
- **reapply:**
  - After 40 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-sleeved** shirts, pants, hats, and sunglasses
- **children** under 6 months of age: ask a doctor

**Other Information** Store at temperatures below 90°F (30°C). Protect the product in this container from excessive heat and direct sun.

**Inactive Ingredients** Aqua, coco-caprylate/caprate, glycerine, coconut alkane, simmondsia chinensis (jojoba) seed oil, polyglyceryl-3-polyricinoleate, cera alba (beeswax), isostearic acid, polyhydroxy stearic acid, maltodextrin, matricaria chamomilla (German chamomile extract), phenylpropanol, propanediol, caprylyl glycol, tocopherol (Vitamin E), ethylhexylglycerin, cetyl phosphate, sodium chloride, disodium EDTA

**Questions?** [contact@thermasunskin.com](mailto:contact@thermasunskin.com)

Made in USA with Australian Zinc Oxide

[www.thermasunskin.com](http://www.thermasunskin.com) 



X002HCJE1B

Distributed by: AstiVita Ltd 1821 Ipswich Rd, Rocklea 4106, Queensland, Australia

## THERMASUN ZINXATION MINERAL ZINC FACIAL SUNSCREEN - ACNE PRONE SKIN SPF-50

zinc oxide lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:80982-002

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 g in 120 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
JOJOBA OIL (UNII: 724GKU717M)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)	
PHENYLPROPANOL (UNII: 0F89703O4M)	
PROPANEDIOL (UNII: 5965N8W85T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80982-002-37	120 g in 1 TUBE; Type 0: Not a Combination Product	11/02/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/02/2020	

Labeler - ASTIVITA LIMITED (742799513)

Establishment

Name	Address	ID/FEI	Business Operations
ASTIVITA LIMITED		742799513	label(80982-002)

Revised: 1/2022

ASTIVITA LIMITED