

**ZINC FIVE-O 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.*

-----  
**ZINC FIVE-O SPF-50**

**ACTIVE INGREDIENT**

ZINC OXIDE 25%

**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 15 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.

## INACTIVE INGREDIENTS

Coco-caprylate/caprates, glycerine, coconut alkane, simmondsia chinensis (jojoba) seed oil, polyglyceryl-3-polyricinoleate, cera alba (beeswax), isostearic acid, polyhydroxy stearic acid, maltodextrin, phenylpropanol, propanediol, caprylyl glycol, tocopherol, ethylhexylglycerin, cetyl phosphate, sodium chloride, disodium EDTA

**ZINC**  
**FIVE-0**

**ZINXATION**

AUSTRALIAN MINERAL  
**SUNSCREEN**

FACE AND BODY

**SPF 50**

- Broad Spectrum SPF 50
- Formulated in Australia
- Sensitive Skin
- Water Resistant 40 minutes

SAFE

# ZINC FIVE-0

Zinc Five-0 was created to provide Australians with world leading mineral sun protection at an affordable price. Our sunscreen is formulated in Australia and made from 100% Australian Zinc Oxide.

## Drug Facts

Active Ingredient	Purpose
Zinc Oxide (25.0%)	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 15 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. Protect the product in this container from excessive heat and direct sun.

**Inactive Ingredients** Water, coco-caprylate/caprate, glycerine, coconut alkane, simmondsia chinensis (jojoba) seed oil, polyglyceryl-3-polyricinoleate, cera alba (beeswax), lauric acid, polyhydroxy stearic acid, maltodextrin, phenylpropanol, crotonal, cetylalcohol, incothanol.

ethylhexylglycerin, cetyl phosphate, sodium chloride, disodium EDTA

Questions? contact@zincfive0.com

EcoCert  Approved Active Ingredient

www.zincfive0.com 



X002ANAKBF

## ZINC FIVE-O SPF-50

zinc oxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80982-003
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 240 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)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
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:80982-003-39	240 g in 1 TUBE; Type 0: Not a Combination Product	11/20/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/20/2020	

**Labeler** - ASTIVITA LIMITED (742799513)

## Establishment

Name	Address	ID/FEI	Business Operations
ASTIVITA LIMITED		742799513	label(80982-003)

Revised: 1/2022

ASTIVITA LIMITED