

ZINC FIVE-O SPF-50- zinc oxide lotion
ANTARIA PTY 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.

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/caprate, 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

 REEF SAFE

6.7 fl. oz. / 200 mL

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

<i>Active Ingredient</i>	<i>Purpose</i>
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, propanediol, caprylyl glycol, tocopherol, 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:60396-202
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 100 mL

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:60396-202-12	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/26/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/26/2019	

Labeler - ANTARIA PTY LTD (740611405)

Revised: 1/2020

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