ZINXATION SUNSCREEN 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.

ZINXATION SUNSCREEN LOTION 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

- Avoid prolonged exposure in the sun.
- Wear protective clothing-hats and sunglasses.
- Do not swallow.
- For external use only.
- Avoid contact with eyes.
- If a rash or irritation occurs discontinue use.

DIRECTIONS:

- Apply generously to all areas 20 minutes before sun exposure.
- Reapply every 2 hours or after swimming.

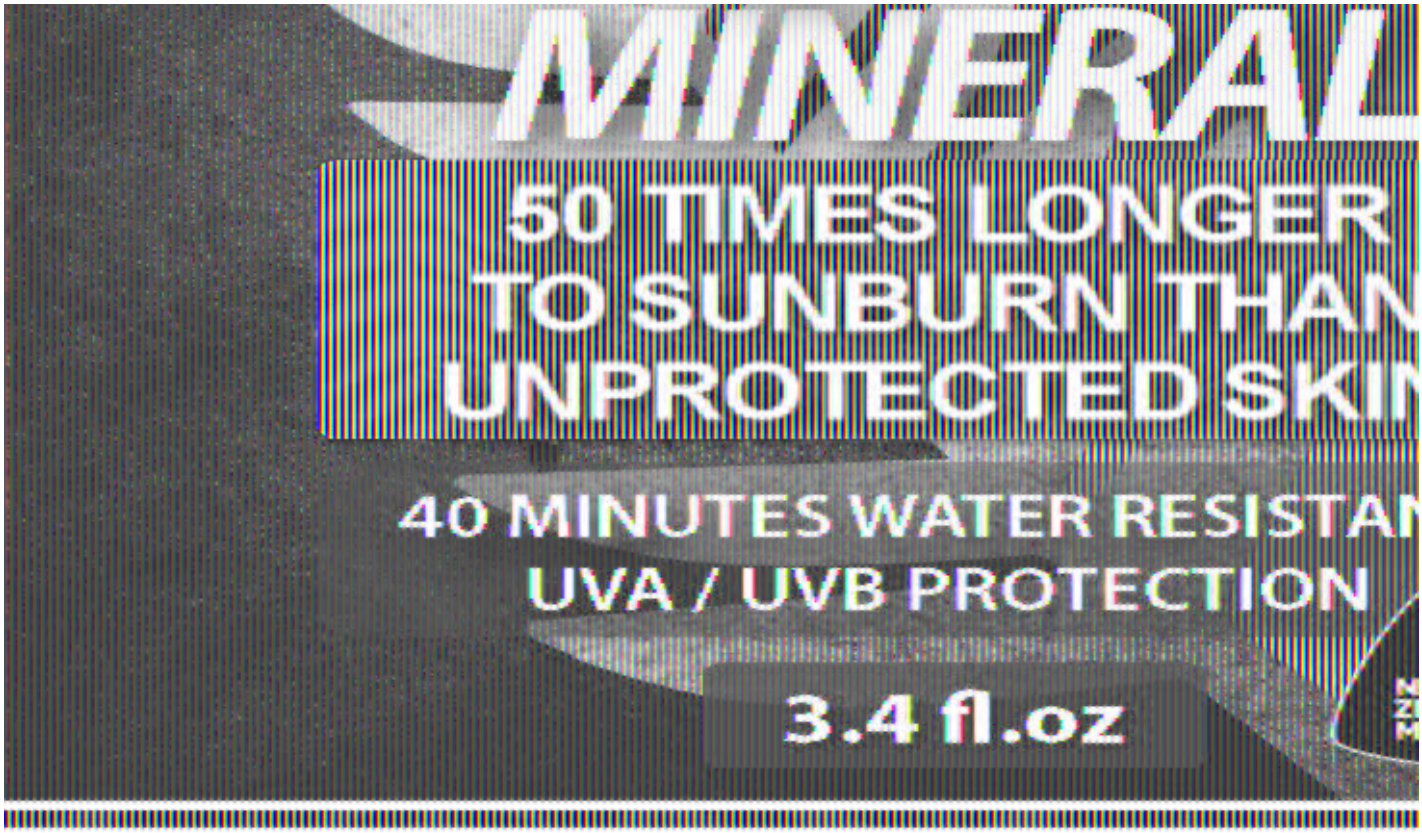
INACTIVE INGREDIENTS

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

QUESTIONS OR COMMENTS?

Call +61 73726 2030


Astia
ZINXATION
FACE & BO
SUNSCREEN LOT
100% ZINC LEAR
ACTIVE INGREDIENT
BROAD SPECTRU
SPF 50



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

+617 3726 2000

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: Water, 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

Manufactured by Alaron Products Ltd,
13 Bolt Road, Tahunanui, Nelson, New Zealand

EcoCert Approved Active Ingredient

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X001W2SIVT

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ZINXATION SUNSCREEN SPF-50
zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80982-001
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 g

Inactive Ingredients

Ingredient Name	Strength
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:80982-001-38	100 g in 1 TUBE; Type 0: Not a Combination Product	07/16/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/16/2018	

Labeler - ASTIVITA LIMITED (742799513)

Establishment

Name	Address	ID/FEI	Business Operations
ASTIVITA LIMITED		742799513	label(80982-001) , manufacture(80982-001)

Revised: 7/2021

ASTIVITA LIMITED