

PREMIUM MINERAL SUNSCREEN BROAD SPECTRUM SPF 30- zinc oxide lotion
Eden Brands

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.

Premium Mineral Sunscreen Broad Spectrum SPF 30

Active ingredients Purpose

Zinc Oxide 22% 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

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Stop use and ask a doctor if rash occurs.

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.

Directions:

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - after 80 minutes of swimming or sweating
 - Immediately after towel drying
 - at least every two hours
 - Children under 6 months of age: ask a doctor
 - **Sun Protection Measures:** Spending time in the sun increases your risk of 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 your time in the sun, especially from 10a.m.-2 p.m.
 - Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive ingredients:

Caprylic/Capric Triglyceride, Vitis Vinifera (grape) Seed Extract, Butyrospermum Parkii (shea) Butter, Silica, Aluminum Starch Octenylsuccinate, Euphorbia Cerifera (Candelilla) Wax/Candelilla Cera, Beeswax/Cera Alba, Glyceryl Isostearate, Brassica Campestris/Aleurites Fordii Oil Copolymer, Polyhydroxystearic Acid, Simmondsia Chinensis (jojoba) Seed Oil, Tocopherol, Carthamus Tinctorious (Safflower) Seed Oil, Cucumis Sativus (Cucumber) Fruit Extract, Glycerin, Water/Aqua, Camellilla sinensis leaf Extract, Rosa Canina Fruit Oil.

SPF 30 Premium Mineral Sunscreen

High Protection

Broad Spectrum SPF 30

Water resistant (80 minutes)

Mineral based Active Ingredient

Net Wt. 3.0oz / 85 g

NO PHTHALATES
NO SYNTHETIC FRAGRANCES

DRUG FACTS

ACTIVE INGREDIENT:	PURPOSE:
Zinc Oxide 22.00%	Sunscreen

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WARNINGS:

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- Do not use on damaged or broken skin.
- Stop use and ask a doctor if rash occurs.
- When using this product keep out of eyes. Rinse with water to remove.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

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 - limit your time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses.

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun.

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MADE IN AUSTRALIA

Distributed by Eden Brands Inc.,
New York, NY 10282, United States.

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NEW YORK

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SPF 30
Premium Mineral
Sunscreen

HIGH PROTECTION

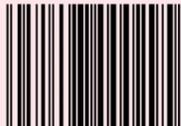
Safe and Gentle
for the Entire Family



Broad Spectrum SPF 30
Water Resistant (80 Minutes)
Mineral Based Active Ingredients
Pollution Shield

Gentle Formula For Sensitive Skin
Paraben Free • Phthalate Free
No Added Fragrance

Net Wt. 3.0 oz / 85 g



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FRONT

BACK

39.2mm Ø CENTRE OFFSET RIGHT 0.09mm

PREMIUM MINERAL SUNSCREEN BROAD SPECTRUM SPF 30
zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72113-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	22 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CUCUMBER (UNII: YY7C30VXJT)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
SHEA BUTTER (UNII: K49155WL9Y)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
GLYCERIN (UNII: PDC6A3C0OX)	
ROSA CANINA FRUIT OIL (UNII: CR7307MBQZ)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
CANDELILLA WAX (UNII: WL0328HX19)	
JOJOBA OIL (UNII: 724GKU717M)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72113-101-01	85 g in 1 BOX; Type 0: Not a Combination Product	02/12/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/12/2018	

Labeler - Eden Brands (081062339)**Establishment**

Name	Address	ID/FEI	Business Operations
Baxter Laboratories Pty. Ltd.		740537709	manufacture(72113-101)