

BIOSSANCE SQUALANE MOISTURIZER SPF30- zinc oxide lotion
Amyris, Inc

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.

Active Ingredients

Zinc Oxide 14%

Purpose

Sunscreen

Uses

Helps prevent sunburn

if used as directed with other sun protection measures(see **directions**), decreases the risk of skin cancer and early signs of 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

a doctor if rash occurs

Keep out of reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions





- Apply generously 15 minutes before sun exposure
- reapply 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 value of SPF 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
- use a water-resistant sunscreen if swimming or sweating
- children under 6 months of age:ask a doctor.

Inactive ingredients

Water, Caprylic/Capric Triglyceride, Zinc Oxide, Glycerin, Squalane, Cetearyl Alcohol, Methyl Dihydroabietate, Dipropylene Glycol, Sorbitan Olivatate, Cetyl Palmitate, Coco Glucoside, Phenoxyethanol, Sodium Palmitoyl Proline, Ethyl Ferulate, Isostearic Acid, Lecithin, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Caprylyl/Capryl Glucosides, Butylene Glycol, Nymphaea Alba Flower Extract, Ethylhexylglycerin, Acacia Senegal Gum, Xanthan Gum, Sodium Gluconate, Glucose.

<p>Drug Facts continued</p> <p>• wear long-sleeved shirts, pants, hats, and sunglasses • use a water-resistant sunscreen if swimming or sweating. • Children under 6 months of age: Ask a doctor.</p> <p>Inactive Ingredients Water, Caprylic/Capric Triglyceride, Squalane, Glycerin, Cetearyl Alcohol, Methyl Dihydroabietate, Sorbitan Olivatate, Coco-Glucoside, Cetyl Palmitate, Polyglyceryl-3 Polyricinoleate, Caprylyl/Capryl Glucoside, Nymphaea Alba Flower Extract, Acacia Senegal Gum, Ethyl Ferulate, Xanthan Gum, Sodium Gluconate, Lecithin, Sodium Palmitoyl Proline, Polyhydroxystearic Acid, Ethylhexylglycerin, Phenoxyethanol, Isostearic Acid.</p> <p>Other Information • protect this product from excessive heat and direct sun.</p> <p>Questions/ Comments? Call toll free 1-844-688-5885</p>	<p>BIOSSANCE™</p> <p>SQUALANE + ZINC SHEER MINERAL SUNSCREEN</p> <p>BROAD SPECTRUM SPF 30 UVA/UVB</p> <p><i>Protects & Moisturizes Face PA+++</i></p> <p></p> <p>C30 H62</p> <p>50ML/1.7 FL. OZ.</p> <p></p>	<p>CLEAN. CONSCIOUS. HIGH PERFORMANCE.</p> <p>Sheer daily mineral SPF 30 facial sunscreen blends easily into skin and leaves a light weight finish.</p> <p>NONTOXIC PARABEN FREE PHTHALATE FREE MINERAL OIL FREE FRAGRANCE FREE</p> <p>Dermatologist tested. Non-comedogenic. For all skin types.</p> <p></p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Zinc Oxide 14%.....</td><td>Sunscreen</td></tr></tbody></table> <p>Uses • helps prevent sunburn • if used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early signs of aging caused by the sun.</p> <p>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 a doctor if rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact Poison Control Center right away.</p> <p>Directions • apply generously 15 minutes before sun exposure. • reapply 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 value of SPF 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. – 2 p.m.</p>	Active Ingredients	Purpose	Zinc Oxide 14%.....	Sunscreen
Active Ingredients	Purpose						
Zinc Oxide 14%.....	Sunscreen						

BIOSSANCE SQUALANE MOISTURIZER SPF30

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73517-381
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	14 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
SQUALANE (UNII: GW89575KF9)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
COCO GLUCOSIDE (UNII: ICS790225B)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM PALMITOYL PROLINE (UNII: 64L053FRFO)	
ETHYL FERULATE (UNII: 5B8915UELW)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
NYMPHAEA ALBA FLOWER (UNII: 40KQ7Q535O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ACACIA SENEGAL WHOLE (UNII: QP4QYZ033C)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73517-381-01	1 in 1 CARTON	06/01/2020	
1		20 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:73517-381-02	1 in 1 CARTON	06/01/2020	
3		50 mL in 1 TUBE, WTH APPLICATOR; Type 0: Not a		

2		Combination Product		
3	NDC:73517-381-03	1 in 1 CARTON	06/01/2020	
3		100 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	06/01/2020	

Labeler - Amyris, Inc (185930182)

Revised: 11/2022

Amyris, Inc