

BROAD SPECTRUM SPF50 WATER RESISTANT (80 MINUTES) MINERAL SUNSCREEN UVA UVB PROTECTION STICK FOR KIDS- zinc oxide stick Aruba Aloe Balm NV

Broad Spectrum SPF50+ Water Resistant (80 minutes) Mineral Sunscreen UVA/UVB Protection Stick for Kids

Drug Facts

Active ingredients

Zinc Oxide 20.0%

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 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 a doctor if

- rash occurs.

Keep out of reach of children.

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

Directions

• apply generously 15 minutes before sun exposure. • reapply • after 80 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 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

- protect the product in this container from excessive heat and direct sun.

Inactive ingredients

Candelilla Wax, Caprylic/Capric Triglyceride, Cera Alba (Beeswax), Cocos Nucifera (Coconut) Oil, Myristyl Myristate, C18-20 Alkane, Butyrospermum Parkii (Shea) Butter, C13-14 Alkane, Tridecyl Salicylate, Theobroma Cacao (Cocoa) Seed Butter, Helianthus Annuus (Sunflower) Seed Wax, Tocopheryl Acetate, Fragrance (Parfum), Aloe Barbadensis Leaf Juice (Aloe Vera Gel from Aruba), Sorbitan Oleate, Simmondsia Chinensis (Jojoba) Seed Oil, Triethoxycaprylylsilane.

Package Labeling:

Drug Facts

Active ingredients	Purpose
Zinc Oxide 20.0%	Sunscreen

Uses
 ■ helps prevent sunburn, ■ if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer an 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 a doctor if ■ rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
 ■ apply generously 15 minutes before sun exposure. ■ reapply ■ after 80 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
 ■ protect the product in this container from excessive heat and direct sun.

Inactive ingredients
 Candelilla Wax, Caprylic/Capric Triglyceride, Cera Alba (Beeswax), Cocos Nucifera (Coconut) Oil, Myristyl Myristate, C18-21 Alkane, Butyrospermum Parkii (Shea) Butter, C13-14 Alkane, Tridecyl Salicylate, Theobroma Cacao (Cocoa) Seed Butter, Helianthus Annuus (Sunflower) Seed Wax, Tocopheryl Acetate, Fragrance (Parfum), Aloe Barbadensis Leaf Juice (Aloe Vera Gel from Aruba), Sorbitan Oleate, Simmondsia Chinensis (Jojoba) Seed Oil, Triethoxycaprylylsilane.

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BROAD SPECTRUM SPF50 WATER RESISTANT (80 MINUTES) MINERAL SUNSCREEN UVA UVB PROTECTION STICK FOR KIDS

zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53675-205
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CANDELILLA WAX (UNII: WL0328HX19)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCONUT OIL (UNII: Q9L0073W7L)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
SHEA BUTTER (UNII: K49155WL9Y)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
COCOA BUTTER (UNII: 512OYT1CRR)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
JOJOBA OIL (UNII: 724GKU717M)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53675-205-00	30 mL in 1 CONTAINER; Type 0: Not a Combination Product	03/08/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/08/2022	

Labeler - Aruba Aloe Balm NV (855442273)

Establishment

Name	Address	ID/FEI	Business Operations
Aruba Aloe Balm NV		855442273	manufacture(53675-205)

Revised: 11/2023

Aruba Aloe Balm NV