BROAD SPECTRUM SPF 30 WATER RESISTANT MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream Aruba Aloe Balm NV

Broad Spectrum SPF 30 Water Resistant Mineral Sunscreen

Drug Facts

Active ingredients

Titanium Dioxide 10% Zinc Oxide 8%

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.

- 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: Sun Protection
 Measures.
- 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.

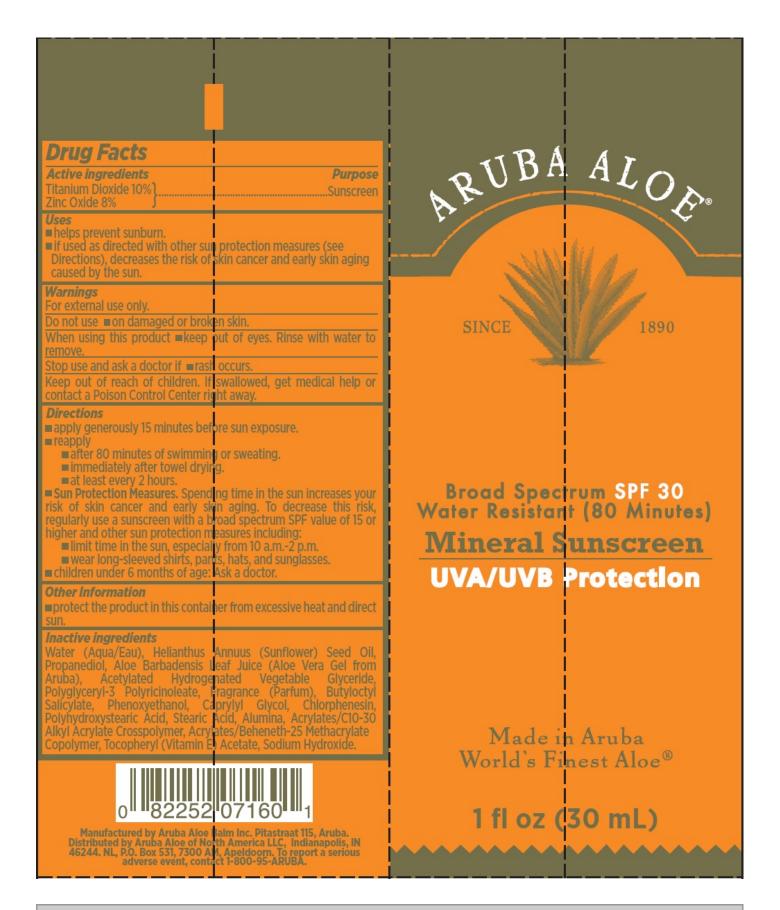
Other Information

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

Inactive ingredients

Water (Aqua/Eau), Helianthus Annuus (Sunflower) Seed Oil, Propanediol, Aloe Barbadensis Leaf Juice (Aloe Vera Gel from Aruba), Acetylated Hydrogenated Vegetable Glyceride, Polyglyceryl-3 Polyricinoleate, Fragrance (Parfum), Butyloctyl Salicylate, Phenoxyethanol, Caprylyl Glycol, Chlorphenesin, Polyhydroxystearic Acid, Stearic Acid, Alumina, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/Beheneth-25 Methacrylate Copolymer, Tocopheryl (Vitamin E) Acetate, Sodium Hydroxide.

Package Labeling:



BROAD SPECTRUM SPF 30 WATER RESISTANT MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53675-183
Pouts of Administration	TORICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	80 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SUNFLOWER OIL (UNII: 3W1JG795YI)		
PROPANEDIOL (UNII: 5965N8W85T)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
CAPRYLYL GLYCOL (UNII: 00YIU5438U)		
CHLORPHENESIN (UNII: 1670DAL4SZ)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
ALUMINUM OXIDE (UNII: LMI26O6933)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53675-183- 30	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	01/01/2019		

Labeler - Aruba Aloe Balm NV (855442273)

Revised: 11/2023 Aruba Aloe Balm NV