BROAD SPECTRUM SPF 50 MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream

Aruba Aloe Balm NV

Broad Spectrum SPF 50+ Mineral Sunscreen

Drug Facts

Active ingredients

Titanium Dioxide 10% Zinc Oxide 10%

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 use a sunscreen with a broad spectrum SPF value of 15 or higher andd 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

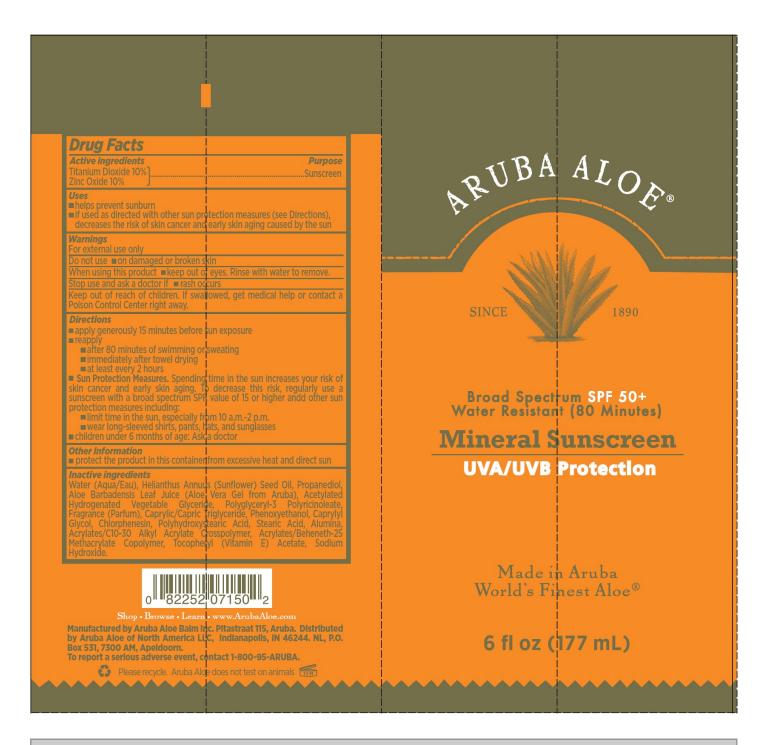
Other Information

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

Inactive ingredients

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), Caprylic/Capric Triglyceride, 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 50 MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:53675-176 Route of Administration TOPICAL

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	100 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)	
ACETATE ION (UNII: 569DQM74SC)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:53675-176- 00	177 mL in 1 TUBE; Type 0: Not a Combination Product	10/25/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	h Marketing Start Marketin Date Dat	
OTC Monograph Drug	M020	10/25/2017	

Labeler - Aruba Aloe Balm NV (855442273)

Establishment					
Name	Address	ID/FEI	Business Operations		
Aruba Aloe Balm NV		855442273	manufacture(53675-176)		

Revised: 11/2023 Aruba Aloe Balm NV