BROAD SPECTRUM SPF 30 WATER RESISTANT (80 MINUTES)- titanium dioxide, zinc oxide cream
Aruba Aloe Balm NV

Broad Spectrum SPF 30 Water Resistant (80 Minutes)

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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.

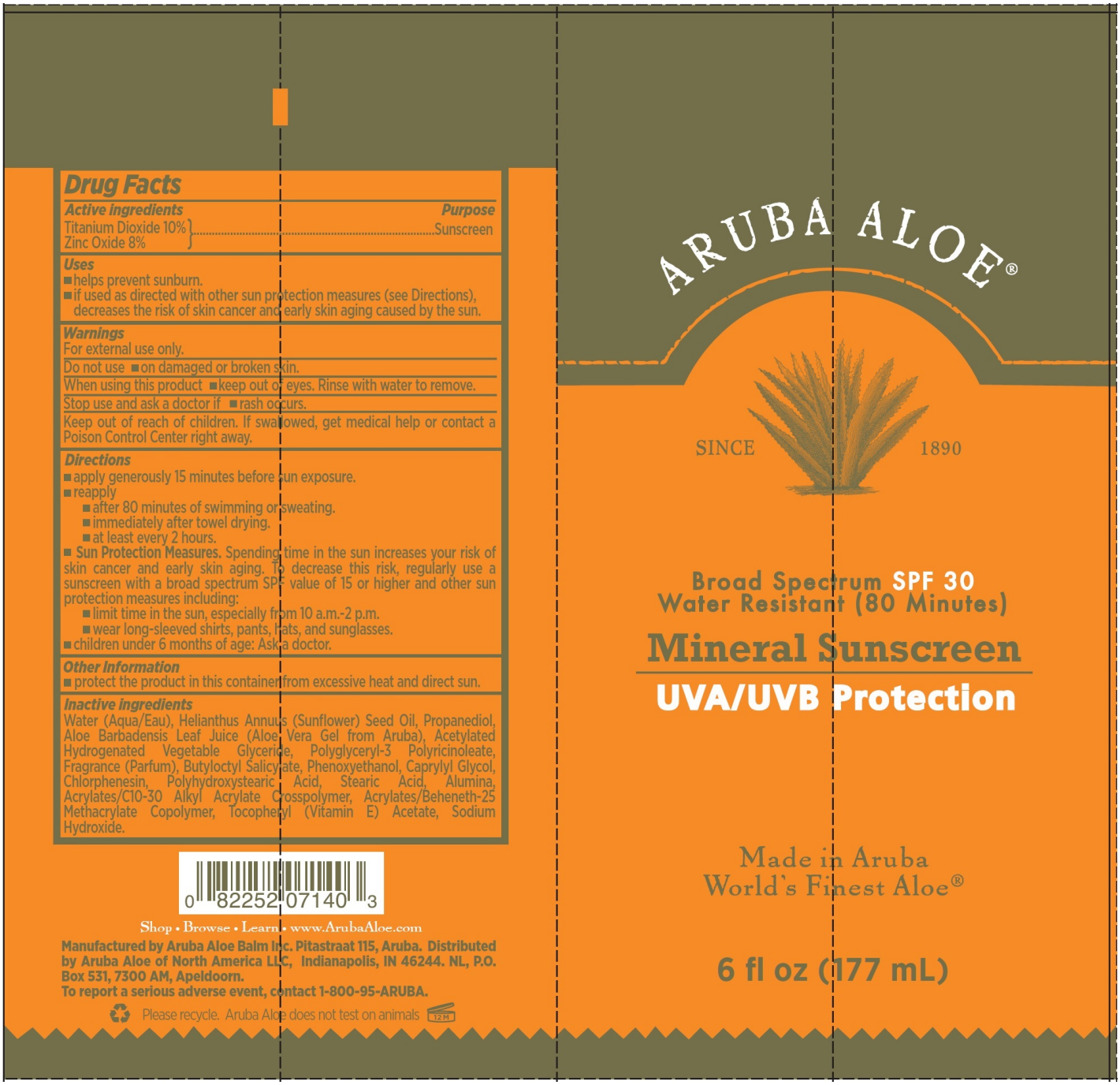
Other Information

- 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 (80 MINUTES)

titanium dioxide, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53675-180
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	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: I670DAL4SZ)	
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:53675-180-00	177 mL in 1 TUBE; Type 0: Not a Combination Product	09/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/01/2018	

Labeler - Aruba Aloe Balm NV (855442273)

Establishment

Name	Address	ID/FEI	Business Operations
Aruba Aloe Balm NV		855442273	manufacture(53675-180)

Revised: 11/2023 Aruba Aloe Balm NV