HYDRATING ALOE RICH SUNCARE SPF 15 BROAD SPECTRUM VERY WATER RESISTANT 80 MINUTES UVA UVB PROTECTION- avobenzone, homosalate, octocrylene, octisalate cream Aruba Aloe Balm NV

Hydrating Aloe Rich Suncare SPF 15 Broad Spectrum Very Water Resistant (80 minutes) UVA/UVB Protection

Drug Facts

Active ingredients

Avobenzone 3% Homosalate 7.34% Octocrylene 5% Octyl Salicylate 5%

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 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

Water (Aqua/Eau), Aloe Barbadensis Leaf Juice (Aloe Vera Gel from Aruba), VP/Eicosene Copolymer, Cetearyl Alcohol, Ceteth-20 Phosphate, Dimethicone, Tocopheryl Acetate (Vitamin E Acetate), Simmondsia Chinensis (Jojoba) Seed Oil, Cocos Nucifera (Coconut) Oil, Caprylyl Glycol, Myristyl Laurate, Glyceryl Laurate, Myristyl Myristate, Fragrance (Parfum), Glyceryl Undecylenate, Carbomer, Aminomethyl Propanol.

Package Labelling:

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Manufactured in Aruba by Aruba Aloe Balm Inc. Pitastraat 115, Aruba, Dutch Caribbean. Toli Free 1-800-95-ARUBA. NL, P.O. Box 531,7300 AM, Apeldoorn.



HYDRATING ALOE RICH SUNCARE [SPF 15]

BROAD SPECTRUM VERY WATER RESISTANT (80 MINUTES) UVA/UVB PROTECTION

2 fl oz (59 mL)

HYDRATING ALOE RICH SUNCARE SPF 15 BROAD SPECTRUM VERY WATER RESISTANT 80 MINUTES UVA UVB PROTECTION

avobenzone, homosalate, octocrylene, octisalate cream

Product	Inform	ation
Product	11110111	lation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:53675-209

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	73.4 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
WATER (UNII: 059QF0KO0R)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
CETETH-20 PHOSPHATE (UNII: 921FTA1500)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
JOJOBA OIL (UNII: 724GKU717M)			
COCONUT OIL (UNII: Q9L0O73W7L)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
MYRISTYL LAURATE (UNII: 58U0NZN2BT)			
GLYCERYL LAURATE (UNII: Y98611C087)			
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)			

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:53675-209- 00	59 mL in 1 TUBE; Type 0: Not a Combination Product	04/11/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/11/2024	

Labeler - Aruba Aloe Balm NV (855442273)

Establishment				
Name	Address	ID/FEI	Business Operations	
Aruba Aloe Balm NV		855442273	manufacture(53675-209)	

Revised: 8/2024 Aruba Aloe Balm NV