

SPF 60 MINERAL SUNSCREEN- titanium dioxide, zinc oxide stick
Derma Care Research Labs, LLC

Aruba SPF 60 Sunscreen Stick

Titanium Dioxide 6%, Zinc Oxide 4.6%

Sunscreen

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.

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 or irritation develops and lasts.

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

Apply liberally 15 minutes before sun exposure and as needed. 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 value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10:00 a.m. - 2:00 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months of age: ask a doctor.

Aluminum hydroxide, beeswax, BHT, butyloctyl salicylate, C12-15 alkyl benzoate, cetyl alcohol, dimethicone, euphoria cerifera (candelilla) wax, isostearic acid, neopentyl glycol diethylhexanoate, ozokerite, paraffin, polyethylene, stearic acid, triethoxycaprylsilane



Drug Facts

Active ingredients Purpose
 Titanium dioxide 6%.....Sunscreen
 Zinc oxide 4.6%.....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

Distributed by:
Aruba Sun International,
 a Delaware Limited Liability Company,
 440 Fentress Blvd.,
 Daytona Beach, Florida 32114

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Drug Facts (continued)

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 or irritation develops and lasts
Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away

Directions • apply liberally 15 minutes before sun exposure and as needed. 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

HINGE SIDE

Drug Facts (continued)

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
 aluminum hydroxide, beeswax, BHT, butyloctyl salicylate, C12-15 alkyl benzoate, cetyl alcohol, dimethicone, euphorbia cerifera (candelilla) wax, isostearic acid, neopentyl glycol diethylhexanoate, ozozerite, paraffin, polyethylene, stearic acid, triethoxycaprylylsilane

HINGE SIDE

SPF 60 MINERAL SUNSCREEN

titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72839-547
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	6 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CANDELILLA WAX (UNII: WL0328HX19)	
NEOPENTYL GLYCOL DIETHYLHEXANOATE (UNII: U68ZV6W62C)	
CERESIN (UNII: Q1LS2UJO3A)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE 200 (UNII: RGS4T2AS00)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
PARAFFIN (UNII: I9O0E3H2ZE)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72839-547-01	14 g in 1 CYLINDER; Type 0: Not a Combination Product	05/23/2023	
2	NDC:72839-547-11	14 g in 1 CYLINDER; Type 0: Not a Combination Product	05/23/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/23/2023	

Labeler - Derma Care Research Labs, LLC (116817470)

Registrant - Derma Care Research Labs, LLC (116817470)

Establishment

Name	Address	ID/FEI	Business Operations
Derma Care Research Labs, LLC		116817470	manufacture(72839-547)

Revised: 11/2023

Derma Care Research Labs, LLC