

**SKIN CARE PRESCRIPTION -
avobenzone, octocrylene, oxybenzone, homosalate, octisalate lotion
Skin Care Physicians, Inc.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients :	Purpose
Avobenzone 3.0%.....	Sunscreen (A)
Octocrylene 4.0%.....	Sunscreen (B)
Oxybenzone 6.0%.....	Sunscreen (A)
Homosalate 15.0%.....	Sunscreen (B)
Octisalate 5.0%.....	Sunscreen (B)

Uses

- High UVB sunburn/UVA protection
- for skin highly sensitive to sunburn
- retains SPF after 80 minutes of activity

Warnings

For External use only

UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using sunscreen.

Directions

- Apply liberally before sun exposure.
- Apply and reapply as directed to avoid lowering protection.
- Reapply after 80 minutes of swimming or sweating and after towel drying. Otherwise reapply at least every 2 hours.
- Children under 6 months; ask a doctor.

Inactive Ingredients

Aqua; Acrylates/C10-30 Alkyl Acrylate Crosspolymer; Sorbitol; Marshmallow Extract; Ivy Extract; Cucumber Extract; Elder Flower; Arnica Extract; EDTA; Aloe Barbadensis Leaf Juice; Isopropyl Palmitate; Stearic Acid; PEG100 Stearate; Dimethicone; Tocopheryl Acetate; Cetyl Alcohol; Glycerol Stearate; C12-15 Alkyl Benzoate; Cetearyl Alcohol, Ceteareth-20; DMDM Hydantoin; Phenoxyethanol Ethylhexyl Glycerin; Triethanolamine; Acrylates/C12-22 Alkylmethacrylates Copolymer; Retinyl Palmitate

SKINCARE PHYSICIANS



**SKINCARE
PRESCRIPTION**

Total Sun Protection
UVA / UVB

Paraben Free
Very Water/Sweat Resistant

SPF-70

116 mL e 4 fl oz.

Drug Facts

Active ingredients	Purpose
Avobenzone 3%	Sunscreen (A)
Octocrylene 4%	Sunscreen (B)
Oxybenzone 6%	Sunscreen (A)
Homosalate 15%	Sunscreen (B)
Octisalate 5%	Sunscreen (B)

Uses ■ High UVB sunburn/UVA protection ■ for skin highly sensitive to sunburn ■ retains SPF after 80 minutes of activity

Warnings For external use only
UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using sunscreen.

When using this product keep out of eyes.
Rinse with water to remove.

Stop use and ask a doctor if skin rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
■ Apply liberally before sun exposure. ■ Apply and reapply as directed to avoid lowering protection.
■ Reapply after 80 minutes of swimming or sweating and after towel drying. Otherwise reapply at least every 2 hours. ■ Children under 6 months: ask a doctor.

Other Information May stain some fabrics

Inactive Ingredients Acrylates/C12-22 Alkylmethacrylates Copolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Arnica Extract, Aqua (Deionized Water), C12-15 Alkyl Benzoate, Cetearyl Alcohol, Cetearth-20, Cetyl Alcohol, Cucumber Extract, Dimethicone, DMDM Hydantoin, Elder Flower, Ethylhexylglycerin, Glyceryl Stearate, Isopropyl Palmitate, Ivy Extract, Marshmallow Extract, PEG 100 Stearate, Phenoxyethanol, Retinyl Palmitate, Sorbitol, Stearic Acid, Tetrasodium EDTA, Tocopheryl Acetate, Triethanolamine

Questions or comments? SkinCarePhysicians, Inc. Chestnut Hill MA 02467 www.skincarephysicians.net

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May stain some fabrics

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52347-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	3.40 g in 114.4 g
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	17.01 g in 113.4 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.06 g in 113.4 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 113.4 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	4.54 g in 113.4 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERYL DISTEARATE (UNII: 73071MW2KM)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Dimethicone (UNII: 92RU3N3Y1O)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
ACAI (UNII: 46AM2VJ0AW)	
CRANBERRY (UNII: 0MVO31Q3QS)	
CUCUMBER (UNII: YY7C30VXJT)	
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T)	
ARNICA MONTANA (UNII: O80TY208ZW)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
EDETIC ACID (UNII: 9G34HU7RV0)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:52347-111-01	116 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	06/23/2010		

Labeler - Skin Care Physicians, Inc. (064598985)

Revised: 10/2010

Skin Care Physicians, Inc.