SIMPLI DAY ALL IN ONE SMARTCREAM SPF 42- zinc oxide, octisalate, octocrylene, ensulizole cream SIMPLI SKIN MD LLC

SIMPLI DAY: All-In-One SmartCream SPF-42

Drug Facts

Active Ingredients

Zinc Oxide 5%

Octisalate 5%

Octocrylene 5%

Ensulizole 4%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see), decreases the risk of skin cancer and early skin aging caused by the sun. **Directions**

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 doctor

if rash or irritation occurs

Keep out of each of children.

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

Directions

- Apply liberally each morning 15 minutes before sun exposure.
- During 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 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-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: ask a doctor

Other information

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

Inactive ingredients

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Ascorbyl Palmitate (Vitamin C), Bakuchiol, Camellia Sinensis (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Capryloyl Glycerin/Sebacic Acid Copolymer, Ceramide NG, Cetearyl Alcohol, Citrullus Lanatus (Watermelon) Extract, Cucumis Sativus (Cucumber) Fruit Extract, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone, Ethylhexyl Palmitate, Ethylhexylglycerin, Ferulic Acid, I-Glutathione, Glycerin, Glyceryl Stearate, Hyaluronic Acid, Hydroxypropyl Cyclodextrin, Lamanaria Digitata (Sea Kelp) Extract, Lecithin, Niacinamide, Palmitoyl Tripeptide-38, Panthenol (Vitamin B5), Phenoxyethanol, Plankton Extract, Polyhydroxystearic Acid, Polypodium Leucotomos Extract, Polysorbate-20, Stearic Acid, Tocopherol (Vitamin E), Tridecyl Salicylate, Zemea (Corn) Propanediol

Questions or comments?

Visit www.simpliskinmd.com

Package Labeling:



Drug Facts	
Active Ingredients	Purpose
Zinc Oxide 5%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 5%	Sunscreen
Ensulizole 4%	Sunscreen

Uses

 Helps prevent sunburn.
 If used as directed with other sun protection measures (see **Directions**),

Inactive ingredients Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Ascorbyl Palmitate (Vitamin C), Bakuchiol, Camellia Sinensis (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Capryloyl Glycerin/Sebacic Acid Copolymer, Ceramide NG, Cetearyl Alcohol, Citrullus Lanatus

(Watermelon) Extract. Cucumis Sativus

Drug Facts (continued)



Simpli Day Smart Cream® is not your ordinary sunscreen. It is an all-in-one Smartcream® that combines the leading scientifically proven ingredients into one lightweight transparent formulation to simplify your skincare routine. Dermatologist-developed and clinically tested. Available only from physicians, because we know your doctor knows what is best.

decreases the risk of skin cancer and (Cucumber) Fruit Extract, early skin aging caused by the sun. Cyclopentasiloxane, Cyclotetrasiloxane, Warnings Dimethicone, Ethylhexyl Palmitate, For external use only Ethylhexylglycerin, Ferulic Acid, Do not use on damaged or broken skin I-Glutathione, Glycerin, Glyceryl When using this product keep out of Stearate, Hyaluronic Acid, eves. Rinse with water to remove. Hydroxypropyl Cyclodextrin, SIMPLI DAY SMART CREAM® HIGHLIGHTS: Stop use and ask doctor Lamanaria Digitata (Sea Kelp) Extract, if rash or irritation occurs Lecithin, Niacinamide, Palmitovl Keep out of reach of children. Tripeptide-38, Panthenol (Vitamin B5), **ANTIOXIDANTS** If swallowed, get medical help or **ALL-IN-ONE** Phenoxyethanol, Plankton Extract, Vitamin C contact a Poison Control Center Polyhydroxystearic Acid, **SMARTCREAM** Vitamin E right away Polypodium Leucotomos Extract, Ferulic acid Directions Polysorbate-20, Stearic Acid, Niacinamide Tocopherol (Vitamin E), Tridecyl Apply liberally each morning 15 **Broad Spectrum** Glutathione minutes before sun exposure. Salicylate, Zemea (Corn) Propanediol Sunscreen SPF 42 During sun exposure, reapply: Questions or comments? Water Resistant · after 80 minutes of swimming Visit www.simpliskinmd.com MOISTURIZERS (80 minutes) or sweating Hyaluronic acid · immediately after towel drying Vitamin B5 **Antioxidants** · at least every 2 hours Ceramides Sun Protection Measures: Spending Moisturizer time in the sun increases your risk of **Anti-Aging** skin cancer and early skin aging. ANTI-AGING To decrease this risk, regularly use a Bakuchiol sunscreen with a broad-spectrum SPF Polypodium Leucotomos of 15 or higher and other sun Liposomal Photolyase protection measures including: Peptides · limit time in the sun, especially from 10 a.m. - 2 p.m. **Dermatologist Developed** · wear long-sleeve shirts, pants, hats, and sunglasses Children under 6 months: ask a doctor Other information · Protect the product in this container from excessive heat and direct sun Contents stored in airless pump system **Broad Spectrum UVA/UVB Sunscreen** to optimize ingredient potency. Before first use, pump slowly approximately 10-15 times until Lightweight and Transparent Non-Comedogenic/Won't Block Pores product dispenses appropriately Fragrance-Free • Cruelty-Free
Hypoallergenic • Clinically Tested Product Color: Off-white Cream Manufactured in the USA for Simpli Skin MD LLC Fullerton, CA 92833 **Available Only From Physicians** 1.7 FL OZ / 50 mL Barcode NDC

SIMPLI DAY ALL IN ONE SMARTCREAM SPF 42

zinc oxide, octisalate, octocrylene, ensulizole cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82733-294
Route of Administration	TOPICAL		

EXP LOT

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	50 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	40 mg in 1 mL

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BAKUCHIOL (UNII: OT12HJU3AR)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CERAMIDE NG (UNII: C04977SRJ5)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATERMELON (UNII: 231473QB6R)	
CUCUMBER (UNII: YY7C30VXJT)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FERULIC ACID (UNII: AVM951ZWST)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
HYALURONIC ACID (UNII: S270N0TRQY)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PALMITOYL LYSYLDIOXYMETHIONYLLYSINE (UNII: T7A529FB8O)	
PANTHENOL (UNII: WW9CM0067Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIDECYL SALICYLATE (UNII: AZ Q08K38Z1)	
CORN (UNII: 0N86727070)	

Ш	Packaging			
	tem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:82733-294- 00	1 in 1 BOX	05/20/2022	
		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/20/2022	

Labeler - SIMPLI SKIN MD LLC (113704769)

Revised: 11/2023 SIMPLI SKIN MD LLC