

CREMO SUNSCREEN- avobenzone, octisalate, octocrylene lotion

Cremo company

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.

Face Lotion with Sunscreen SPF 20

Drug Facts

Active ingredients

Avobenzone 3%

Octisalate 5%

Octocrylene 7.5%

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 broken or damaged 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 liberally 15 minutes before sun exposure
- reapply:
- at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating
- Sun Protections 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Other information

Protect this product from excessive heat and direct sun

Inactive ingredients Acrylamide/Sodium Acryloyldimethyl Taurate Copolymer, Aloe Vera Juice, Water (Aqua), Green Tea Extract, Carbomer, Cetyl Alcohol, Cyclopentasiloxane, Cyclotetrasiloxane, Dimethicone, Ethylhexylglycerin, Sunflower Oil, Isohexadecane, Phenoxyethanol, Polysorbate 20,

Polysorbate-80, Propylene Glycol, Pomegranate Extract, Stearic Acid, Tocopheryl Acetate (Vitamin E), Triethanolamine

cremocompany.com

Distributed by Cremo Company LLC, Laguna Beach, CA 92651

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Cremo®

Astonishingly Superior®

FACE LOTION WITH SUNSCREEN

PREVENTATIVE FORMULA

HYDRATES & NOURISHES WHILE PROTECTING SKIN FROM THE ELEMENTS

BROAD SPECTRUM SPF 20

MOISTURIZER + SUN PROTECTION

Essential skincare

2 FL OZ (59 mL)

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CREMO SUNSCREEN

avobenzone, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71825-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
WATER (UNII: 059QF0KO0R)	
SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPAS) (UNII: 5F4963KLHS)	
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOHEXADECANE (UNII: 918X10UF1E)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POMEGRANATE (UNII: 56687D1Z4D)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71825-102-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/01/2020	

Labeler - Cremo company (078708508)

