

BROAD SPECTRUM SPF 50 CAREONE- avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion

Careone

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

3% Avobenzone

13% Homosalate

5% Octisalate

7% Octocrylene

4% Oxybenzone

Purpose

Sunscreen

Uses

- helps prevent sunburns

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

Directions

- apply liberally 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 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

Inactive Ingredients

Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Methylparaben, Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isostearate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water

Other Information

- protect this product from excessive heat and direct sun
- may stain fabrics

CAREone®

*Compare to the active ingredients of Coppertone Ultra Guard Sunscreen Lotion

SUNSCREEN Lotion



Broad Spectrum SPF 50

- Water Resistant (80 min)
- Moisturizing formula
- Hypoallergenic

8 FL OZ (237 mL)

Drug Facts

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 13%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	Sunscreen
Oxybenzone 4%	Sunscreen

Uses • helps prevent sunburn • higher SPF gives more sunburn protection • retains SPF after 80 minutes of activity in the water • provides high protection against sunburn

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 last,

Keep out of 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. • Children under 6 months of age: ask a doctor. • 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. • For sunscreen use: • apply to all skin exposed to the sun. • Reapply as needed or after towel drying, swimming, or sweating.

Other information • protect the product in this container from excessive heat and direct sun • may stain fabrics.

Inactive ingredients Aluminum Starch Octenylsuccinate, Benzyl Alcohol, Carbomer, Dimethicone, Disodium EDTA, Fragrance, Methylparaben, Polyglyceryl-3 Distearate, Propylparaben, Sorbitan Isocelate, Sorbitol, Stearic Acid, Tocopherol, Triethanolamine, VP/Eicosene Copolymer, Water.

Questions? 1-877-846-9949

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BROAD SPECTRUM SPF 50 CAREONE

avobenzone 3% homosalate 13% octisalate 5% octocrylene 7% oxybenzone 4% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-736
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

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	13 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 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TROLAMINE (UNII: 9O3K93S3TK)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-736-06	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/25/2018	

Labeler - Careone (809183973)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(41520-736) , label(41520-736)