SUNSCREEN SPF 30- avobenzone 3.0% homosalate 10.0% octisalate 5.0% octocrylene 10.0% 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

Actives

Avobenzone 3.0%

Homosalate 10.0%

Octisalate 5.0%

Octocrylene 10.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn • Higher SPF gives more sunburn protection•retains SPF after 80 minutes of activity in the weater or sweating • provides hight 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 lasts

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 measure 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Benzyl Alcohol, Caprylic/Capric Triglyceride, Chlorphenesin, Diethylhexyl Syringylidemaionate, Disodium EDTA, Ethylhexyl Palmitate, Fragrance, Oieth-3, Polyamide-8, Retinyl Palmitate, Sodium Ascorbyl Phosphate, Sorbitol, Tocopherol, Triethanolamine, Water.

SUNSCREEN SPF 30

avobenzone 3.0% homosalate 10.0% octisalate 5.0% octocrylene 10.0% lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-347
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	10 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
OLETH-3 (UNII: BQZ26235UC)	
NEOPENTYL GLYCOL (UNII: QI80HXD6S5)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
SORBITOL (UNII: 506T60A25R)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:41520-347-06	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/25/2017	

Labeler - CareOne (809183973)

Registrant - Product Quest Mfg, LLC (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg, LLC		927768135	manufacture(41520-347) , label(41520-347)

Revised: 7/2018

CareOne