

CAREONE 7-IN-1 ANTI-AGING VITAMIN- avobenzone, octisalate and octocrylene cream
American Sales 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.

CareOne[®] anti-aging vitamin complex

Active ingredient

Avobenzone 3.0

Octisalate 5.0%

Octocrylene 8.0%

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

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

Directions

- Apply liberally 15 minutes before sun exposure.
- Children under 6 months of age: ask a doctor
- **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

Other Information

- protect the product in this container from excessive heat and direct sun

Inactive Ingredients

water, glycerin, isopropyl isostearate, boron nitride, sodium carboxymethyl beta-glucan, polyacrylamide, C13-14 isoparaffin, laureth-7, cetyl alcohol, stearyl alcohol, cyclopentasiloxane, dimethiconol, dimethicone, cetearyl alcohol, cetearyl glucoside, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, sorbitan stearate, panthenol (pro-vitamin B5), behenyl alcohol, tocopheryl acetate (vitamin E), benzyl alcohol, disodium EDTA, PEG-100 stearate, stearic acid, ascorbyl tetraisopalmitate, magnesium aspartate, zinc gluconate, copper gluconate, calcium gluconate, dihydroxyacetone

Package/Label Principal Display Panel

CareOne[®] anti-aging vitamin complex
7-in-1 broad spectrum SPF15 sunscreen

fragrance free

7 anti-aging treatments in 1 vitamin and antioxidant moisturizer
+ broad spectrum SPF15 protection for younger-looking skin

1.7 FL OZ (50 mL)

DISTRIBUTED BY:

AMERICAN SALES COMPANY

4201 WALDEN AVENUE

LANCASTER, NY 14086

www.care1.info

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Quality guaranteed or your money back.

Manufactured in Israel

2F692 D4 C2

<p>Drug Facts</p> <p>Active Ingredients</p> <table border="0"> <tr> <td>Avobenzone, 3.0%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate, 6.0%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene, 6.0%</td> <td>Sunscreen</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> 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 <p>Warnings</p> <p>For external use only.</p> <p>Do not use on • damaged or broken skin.</p> <p>When using this product • keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor • if rash occurs.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure. Children under 6 months of age: ask a doctor 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: <ul style="list-style-type: none"> limit time in the sun, especially from 10 a.m. – 2 p.m. wear long-sleeved shirts, pants, hats and sunglasses <p>Other Information • protect the product in this container from excessive heat and direct sun</p> <p>Inactive Ingredients water, glycerin, isopropyl isostearate, boron nitride, sodium carboxymethyl beta-glucan, polyacrylamide, C13-14 isoparaffin, laureth-7, cetyl alcohol, stearyl alcohol, cyclopentasiloxane, dimethiconol, dimethicone, cetearyl alcohol, cetearyl glucoside, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, sorbitan stearate, panthenol (pro-vitamin B5), behenyl alcohol, tocopheryl acetate (vitamin E), benzyl alcohol, disodium EDTA, PEG-100 stearate, stearic acid, ascorbyl tetraisopalmitate, magnesium aspartate, zinc gluconate, copper gluconate, calcium gluconate, dihydroxyacetone</p>	Avobenzone, 3.0%	Sunscreen	Octisalate, 6.0%	Sunscreen	Octocrylene, 6.0%	Sunscreen	<p>CAREONE</p> <p>anti-aging vitamin complex</p> <p>7-in-1 broad spectrum SPF15 sunscreen fragrance free</p> <p>For those who are concerned about exposure to the sun and the main cause of premature visible aging, this fragrance-free, color-free facial moisturizer provides 7 anti-aging treatments in 1 formulation, plus extra protection against sun damage.</p> <ol style="list-style-type: none"> Line Reduction: Diminishes the appearance of fine lines and wrinkles Moisturizing Nourishment: For a healthy and radiant glow Tone Improvement: Evens out skin color, reducing the appearance of age spots Gentle Exfoliation: Smooths and evens out skin texture Refinement of Pores: Minimizes the appearance of pores Defense Against Free Radicals: Prevents damage to skin's surface Delicate Lifting: Hydrates the skin for a firmer appearance <p>RESULTS: Younger-looking skin that appears more resilient to aging.</p>	<p>CAREONE</p> <p>anti-aging vitamin complex</p> <p>7-in-1 broad spectrum SPF15 sunscreen fragrance free</p> <p>7 anti-aging treatments in 1 vitamin and antioxidant moisturizer + broad spectrum SPF15 protection for younger-looking skin</p> <p>1.7 FL OZ (50 mL)</p>	<p>CAREONE</p> <p>anti-aging vitamin complex</p> <p>7-in-1 broad spectrum SPF15 sunscreen fragrance free</p> <p>Directions for Use: Apply liberally on face and neck as often as necessary each day to help protect your skin from harmful UV rays while keeping skin soft and smooth. Gentle enough for every day use. Designed to replace your moisturizer and specialty skin care products.</p> <p>This Exclusive Formulation Is:</p> <ul style="list-style-type: none"> Dermatologist Tested Non-Comedogenic (won't clog pores) Color and Fragrance Free Oil Free Fast Absorbing <p>DISTRIBUTED BY: AMERICAN SALES COMPANY 4201 WALDEN AVENUE LANCASTER, NY 14086 www.care1.info © 2012 SES Brands, Inc. Quality guaranteed or your money back. Manufactured in Israel 2F692 D4 C2</p>
Avobenzone, 3.0%	Sunscreen								
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Carton Label

CAREONE 7-IN-1 ANTI-AGING VITAMIN

avobenzone, octisalate and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-869
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mL in 100 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 mL in 100 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	8 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

STEARYL ALCOHOL (UNII: 2KR89I4HIY)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
DIMETHICONOL (250000 MW) (UNII: RKI3S914RT)
DIMETHICONE (UNII: 92RU3N3Y1O)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYLPARABEN (UNII: A2I8C7HI9T)
ETHYLPARABEN (UNII: 14255EXE39)
BUTYLPARABEN (UNII: 3QPIIU3FV8)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)
PANTHENOL (UNII: WV9CM0O67Z)
DOCOSANOL (UNII: 9G1OE216XY)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
BENZYL ALCOHOL (UNII: LKG8494WBH)
EDETATE DISODIUM (UNII: 7FLD91C86K)
PEG-100 STEARATE (UNII: YD01N1999R)
STEARIC ACID (UNII: 4ELV7Z65AP)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
MAGNESIUM ASPARTATE (UNII: R17X820ROL)
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)
COPPER GLUCONATE (UNII: RV823G6G67)
CALCIUM GLUCONATE (UNII: SQE6VB453K)
DIHYDROXYACETONE (UNII: O10DDW6JOO)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-869-24	1 in 1 CARTON		
1		50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/11/2012	

Labeler - American Sales Company (809183973)