

TOPCARE DAILY FACIAL- avobenzone, octocrylene cream

Topco Associates LLC

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.

TopCare® Daily Facial Moisturizer

Active ingredient

Avobenzone 3.0%

Octocrylene 10.0%

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, diisopropyl adipate, cyclopentasiloxane, glycerin, glyceryl stearate, PEG-100 stearate, titanium dioxide, alumina, simethicone, polymethyl methacrylate, phenoxyethanol, benzyl alcohol, triethanolamine, acrylates/C10-30 alkylacrylate crosspolymer, tocopheryl acetate (vitamin E), carbomer, disodium EDTA

Package/Label Principal Display Panel - Carton Label

TopCare®

Daily Facial Moisturizer Broad Spectrum SPF15 Sunscreen

non-greasy and lightweight

protects from UVA and UVB rays

non-comedogenic (won't clog pores)


fragrance-free and paba-free

dermatologist tested

*Compare to Cetaphil® Daily Facial Moisturizer SPF 15 Ingredients

4 FL OZ (118 mL)

DISTRIBUTED BY TOPCO
ASSOCIATES LLC
7711 GROSS POINT ROAD,
SKOKIE, IL 60077 © TOPC ELL512
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<p style="text-align: center;">TopCare. Daily Facial Moisturizer Broad Spectrum SPF15 Sunscreen</p> <div style="border: 1px solid black; padding: 5px;"> <p>Drug Facts</p> <table border="0"> <tr> <td>Active ingredients</td> <td>Purpose</td> </tr> <tr> <td>Avobenzone 3.0%.....</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene 10.0%.....</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 <i>Directions</i>), 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, diisopropyl adipate, cyclopentasiloxane, glycerin, glyceryl stearate, PEG-100 stearate, titanium dioxide, alumina, simethicone, polymethyl methacrylate, phenoxyethanol, benzyl alcohol, triethanolamine, acrylates/C10-30 alkyl acrylate copolymer, tocopheryl acetate (vitamin E), carbomer, disodium EDTA</p> <div style="text-align: center;">  <p>DISTRIBUTED BY TOPCO ASSOCIATES LLC 7711 GRASS POINT ROAD, SKOKIE, IL 60077 © TOPC ELL512 QUESTIONS? 1-888-423-0139 topcare@topco.com</p> </div> <div style="border: 1px solid black; padding: 2px; font-size: 8px;"> <p>This TOPCARE® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.</p> </div> </div>	Active ingredients	Purpose	Avobenzone 3.0%.....	Sunscreen	Octocrylene 10.0%.....	Sunscreen	<p style="text-align: center;">TopCare. Daily Facial Moisturizer Broad Spectrum SPF15 Sunscreen</p> <p>Replenishes moisture and effectively nourishes your skin without a greasy after feel</p> <p>Reduces appearance of fine lines and wrinkles</p> <p>Prevents future damage with broad spectrum protection from the sun's UVA and UVB rays</p> <p>Directions for use: apply daily to face and neck, away from eyes.</p>	<p style="text-align: center;">TopCare. Daily Facial Moisturizer Broad Spectrum SPF15 Sunscreen</p> <p style="text-align: center;"><i>non-greasy and lightweight protects from UVA and UVB rays non-comedogenic (won't clog pores) fragrance-free and para-free dermatologist tested</i></p> <div style="background-color: #90EE90; text-align: center; padding: 5px;"> <p>*Compare to Cetaphil® Daily Facial Moisturizer SPF 15 Ingredients</p> </div> <div style="background-color: #ADD8E6; text-align: center; padding: 20px;"> <p>4 FL OZ (118 mL)</p> </div>	<p style="text-align: center;">TopCare. Daily Facial Moisturizer Broad Spectrum SPF15 Sunscreen</p> <p>Importance of daily sunscreen protection: Protects from the sun's damaging UVA rays that are responsible for premature lines and wrinkles</p> <p>Shields from the sun's damaging UVB rays, which cause dangerous sunburns and skin cancers</p> <p>Restores and improves your skin's ability to retain moisture</p> <p style="text-align: right; font-size: 8px;">*This product is not manufactured or distributed by Galderma®, owner of the registered trademark Cetaphil®</p>
Active ingredients	Purpose								
Avobenzone 3.0%.....	Sunscreen								
Octocrylene 10.0%.....	Sunscreen								

Carton Label

TOPCARE DAILY FACIAL

avobenzone, octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-326
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
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	10 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
ALUMINUM OXIDE (UNII: LM26O6933)
DIMETHICONE (UNII: 92RU3N3Y1O)
POLY(METHYL ACRYLATE-CO-METHYL METHACRYLATE-CO-METHACRYLIC ACID 7:3:1; 280000 MW) (UNII: 99Q3C7L77T)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BENZYL ALCOHOL (UNII: LKG8494WBH)
TROLAMINE (UNII: 9O3K93S3TK)
CARBOMER INTERPOLYMER TYPE A (55000 MPA.S) (UNII: 59TL3WG5CO)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)
EDETATE DISODIUM (UNII: 7FLD91C86K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-326-02	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2012	

Labeler - Topco Associates LLC (006935977)