

CETAPHIL - octocrylene, avobenzone lotion
Galderma Laboratories, L.P.

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.

Cetaphil® Daily Facial Moisturizer

Active Ingredients

Avobenzone 3%
Octocrylene 10%

Purpose

Avobenzone.....Sunscreen
Octocrylene.....Sunscreen

Use(s)

- 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.

Stop use and ask a doctor if rash occurs.

When using this product keep out of eyes.

Rinse with water to remove.

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.
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours.
- Children under 6 months: ask a doctor

SUN PROTECTION MEASURES: Spending time in the sun increases your risk of 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 10am – 2 pm.
- Wear long-sleeved shirts, pants, hats, and sun glasses.

INACTIVE INGREDIENTS:

Water, Diisopropyl Adipate, Cyclomethicone, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Polymethyl Methacrylate, Phenoxyethanol, Benzyl Alcohol, Acrylates/C10-30 Alkyl Acrylate

Crosspolymer, Tocopheryl Acetate, Carbomer 940, Disodium EDTA, Triethanolamine.

Other Information

- Protect this product from excessive heat and direct sun.
- May stain some fabrics.

Questions?

1-866-735-4137

PRINCIPAL DISPLAY PANEL

| | | | |
|---|---|---|---|
| <p>Drug Facts</p> <p>Active Ingredients Purpose</p> <p>Avobenzone 3%.....Sunscreen</p> <p>Octocrylene 10%.....Sunscreen</p> <p>Use(s)</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>Stop use and ask a doctor if rash occurs.</p> <p>When using this product, keep out of eyes. Rinse with water to remove.</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. ■ Use a water resistant sunscreen if swimming or sweating. ■ Reapply at least every 2 hours. ■ Children under 6 months; ask a doctor. <p>SUN PROTECTION MEASURES: Spending time in the sun increases your risk of 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:</p> <ul style="list-style-type: none"> ■ Limit time in the sun, especially 10am-2pm. ■ Wear long-sleeved shirts, pants, hats and sun glasses. <p>Inactive Ingredients</p> <p>Water, Diisopropyl Adipate, Cyclomethicone, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Polymethyl Methacrylate, Phenoxyethanol, Benzyl Alcohol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Tocopheryl Acetate, Carbomer 940, Disodium EDTA, Triethanolamine</p> <p>Other Information</p> <ul style="list-style-type: none"> ■ Protect this product from excessive heat and direct sun. ■ May stain some fabrics. <p>Questions? 1-866-735-4137</p> |  <p>Cetaphil Daily Facial Moisturizer with sunscreen BROAD SPECTRUM SPF 15</p> <p>FOR ALL SKIN TYPES</p> <p>This light, non-greasy moisturizer nourishes and hydrates your skin while protecting it from the sun's harmful rays.</p> <p>Restores and improves your skin's ability to retain vital moisture.</p> <p>Non-comedogenic Fragrance free / PABA free Dermatologist recommended</p> <p>Actual size</p> |  <p>Daily Facial Moisturizer with sunscreen BROAD SPECTRUM SPF 15</p> <p>Face All skin types</p> <p>Hydrates, nourishes and protects UVA/UVB Protection Non-comedogenic Fragrance free Lightweight, non-greasy</p> <p>4 FL OZ (118 mL)</p> | <p>Cetaphil Daily Facial Moisturizer with sunscreen BROAD SPECTRUM SPF 15</p> <p>FOR ALL SKIN TYPES</p> <p>Importance of daily sunscreen protection:</p> <p>UV rays from the sun are made of UVA and UVB. It is important to protect against both UVA and UVB to help prevent sunburn and other skin damage. Also, broad spectrum sunscreen protection helps decrease early signs of aging caused by the sun when used with other sun protection measures.</p> <p>Use in combination with a complete regimen of Cetaphil cleansers and moisturizers for your daily skin care needs.</p> <p>Distributed by: Galderma Laboratories, L.P. Fort Worth, Texas 76177 USA Cetaphil is a registered trademark of Galderma.</p> <p>Made in Canada</p> <p>cetaphil.com P50935-5</p> |
|  <p>3 02993 92804 1</p> <p>LOT:</p> <p>EXP:</p> | <p>P50935-5</p> | | |

Cetaphil®

**Daily Facial
Moisturizer**

with sunscreen

BROAD SPECTRUM SPF 15

Face All skin types

Hydrates, nourishes and protects

UVA/UVB Protection

Non-comedogenic

Fragrance free

Lightweight, non-greasy

4 FL OZ (118mL)

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Actual size

Cetaphil

Daily Facial

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FOR ALL SKIN TYPES

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P50935-5

LOT:

EXP:



Drug Facts

Active Ingredients **Purpose**
 Avobenzone 3%.....Sunscreen
 Octocrylene 10%.....Sunscreen

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- 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.

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SUN PROTECTION MEASURES: Spending time in the sun increases your risk of 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 10am-2pm.
- Wear long-sleeved shirts, pants, hats and sun glasses.

Inactive Ingredients

Water, Disopropyl Adipate, Cyclomethicone, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Polymethyl Methacrylate, Tocopheryl Acetate (Vitamin E), Triethanolamine, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer 940, Disodium EDTA, Phenoxethanol, Benzyl Alcohol

Other Information

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Questions?

1-866-735-4137



Cetaphil MEN Daily Face Lotion with sunscreen BROAD SPECTRUM SPF 15

Protect your skin from harsh outdoor elements and the effects of your razor.

This lightweight formula absorbs quickly and locks in moisture to strengthen skin's natural moisture barrier. Broad spectrum SPF 15 protection helps decrease early signs of aging caused by the sun when used with other sun protection measures. Perfect for post-shave, it also soothes sensitive skin. The result is healthy, hydrated skin all day or night long. Use after cleansing with Cetaphil Men Daily Face Wash.

Won't clog pores. Non-irritating. No fragrance. Dermatologist developed and tested.

Actual size

Cetaphil
MEN

Cetaphil
MEN

MEN Daily Face Lotion with sunscreen BROAD SPECTRUM SPF 15

Face • For all skin types

Soothes sensitive skin even post-shave
 Hydrates and protects skin without clogging pores

4 FL OZ (118 mL)

Cetaphil
MEN

MEN Daily Face Lotion with sunscreen BROAD SPECTRUM SPF 15

Importance of daily sunscreen protection:
 UV rays from the sun are made of UVA and UVB. It is important to protect against both UVA and UVB to help prevent sunburn.

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 Fort Worth, Texas 76177 USA

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Made in Canada

cetaphil.com P52883-0

Cetaphil®
MEN
Daily Face Lotion
 with sunscreen
BROAD SPECTRUM SPF 15

Face • For all skin types

Soothes sensitive skin even post-shave

Hydrates and protects skin without clogging pores

4 FL OZ (118 mL)

Cetaphil **MEN**

Daily Face Lotion

with sunscreen

BROAD SPECTRUM

SPF 15

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Actual Size

Cetaphil® MEN

Daily Face Lotion

with sunscreen

BROAD SPECTRUM

SPF 15

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Fort Worth, TX 76177 USA

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P52833-0

CETAPHIL

octocrylene, avobenzone lotion

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0299-3928 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 10 g in 100 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 3 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| DIISOPROPYL ADIPATE (UNII: P7E6YFV72X) | |
| CYCLOMETHICONE (UNII: NMQ347994Z) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L) | |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0299-3928-04 | 1 in 1 CARTON | | |
| 1 | | 118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | |
| 2 | NDC:0299-3928-07 | 1 in 1 CARTON | | |
| 2 | | 118 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 04/01/2000 | |

Labeler - Galderma Laboratories, L.P. (047350186)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| G Production Inc. | | 251676961 | MANUFACTURE(0299-3928) |

Revised: 2/2016

Galderma Laboratories, L.P.