

**CETAPHIL DAILY FACIAL MOISTURIZER WITH SUNSCREEN SPF 50- octinoxate, octisalate, octocrylene, oxybenzone, titanium dioxide 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 with sunscreen SPF 50+

Active Ingredients.....Purpose

Octinoxate 7.5%Sunscreen
Octisalate 5%Sunscreen
Octocrylene 7%Sunscreen
Oxybenzone 6%Sunscreen
Titanium Dioxide 5.7%Sunscreen

Uses

Helps prevent sunburn.

Warnings

Skin Cancer/Skin Aging Alert:

Spending time in the sun increases your risk of skin cancer and early aging. This product has been shown to help prevent sunburn, **not** skin cancer or early aging.

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.

Inactive Ingredients

Water, Propylene Glycol, Glycerin, Dimethicone, VP/Eicosene Copolymer, Cyclomethicone, Stearic Acid, Dimethiconol, Potassium Cetyl Phosphate, Glyceryl Stearate, PEG-100 Stearate, Aluminum Hydroxide, Disodium EDTA, Tocopherol, Triethanolamine, Phenoxyethanol, Ethylparaben, Chlorphenesin, Cetyl Alcohol, Carbomer, Methylparaben, Xanthan Gum

Other Information

- Protect this product from excessive heat and direct sun.

Questions?

1-866-735-4137

Principal Display Panel - 1.7oz carton



Drug Facts

| Active Ingredients | Purpose |
|-----------------------|-----------|
| Octinoxate 7.5% | Sunscreen |
| Octisalate 5% | Sunscreen |
| Octocrylene 7% | Sunscreen |
| Oxybenzone 6% | Sunscreen |
| Titanium Dioxide 5.7% | Sunscreen |

Uses

Helps prevent sunburn.

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early aging. This product has been shown to help prevent sunburn, not skin cancer or early skin aging.

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.

Inactive Ingredients

Water, Propylene Glycol, Glycerin, Dimethicone, VP/Eicosene Copolymer, Cyclomethicone, Stearic Acid, Dimethiconol, Potassium Cetyl Phosphate, Glyceryl Stearate, PEG-100 Stearate, Aluminum Hydroxide, Disodium EDTA, Tocopherol, Triethanolamine, Phenoxyethanol, Ethylparaben, Chlorphenesin, Cetyl Alcohol, Carbomer, Methylparaben, Xanthan Gum

Other Information

Protect this product from excessive heat and direct sun.

Questions

1-866-735-4137



GALDERMA
Distributed by
Galderma Laboratories, L.P.
Fort Worth, TX 76177 USA
All trademarks are the property
of their respective owners.

Made in Canada
cetaphil.com

For position only



#1 DOCTOR RECOMMENDED SENSITIVE SKINCARE BRAND



Cetaphil®
Daily Facial
Moisturizer
with Sunscreen SPF 50⁺

Clinically proven to hydrate & nourish skin while delivering residue-free defense against sunburn.

Trusted by Dermatologists for 75 Years



Defends against 5 Signs of Skin Sensitivity

- ✓ Weakened Skin Barrier
- ✓ Dryness
- ✓ Irritation
- ✓ Roughness
- ✓ Tightness

Daily Facial
Moisturizer
with Sunscreen SPF 50⁺

50⁺

Dry to Normal,
Sensitive Skin

All day moisturizer hydrates, smooths, and protects skin from harmful sun exposure



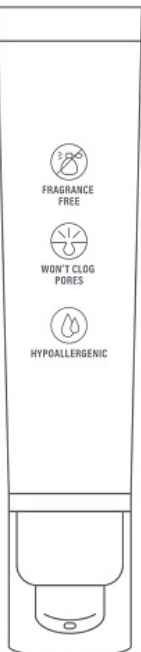
FRAGRANCE FREE



WON'T CLOG PORES



HYPDALLERGENIC



Actual Size

1.7 FL. OZ (50 mL)

P54998-1

LOT:

EXP:

For position only

#1 Doctor Recommended

Sensitive Skincare Brand

Cetaphil®

**Daily Facial
Moisturizer**

with Sunscreen SPF 50

50+

Dry to Normal,
Sensitive Skin

All day moisturizer hydrates,
smooths, and protects skin
from harmful sun exposure

5 Skin Sensitivity Signs

1.7 FL OZ (50 mL)

Distributed by:

Galderma Laboratories, L.P.

Fort Worth, TX 76177 USA

All trademarks are the property of their respective owners.

Made in Canada

cetaphil.com

CETAPHIL DAILY FACIAL MOISTURIZER WITH SUNSCREEN SPF 50

octinoxate, octisalate, octocrylene, oxybenzone, titanium dioxide lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0299-4930 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM) | OCTOCRYLENE | 70 mg in 1 mL |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 60 mg in 1 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 57 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|-----------------|
| WATER (UNII: 059QF0KO0R) | |

| |
|---|
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3) |
| CYCLOMETHICONE (UNII: NMQ347994Z) |
| STEARIC ACID (UNII: 4ELV7Z65AP) |
| DIMETHICONOL (40 CST) (UNII: 343C7U75XW) |
| POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT) |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) |
| PEG-100 STEARATE (UNII: YD01N1999R) |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |
| TOCOPHEROL (UNII: R0ZB2556P8) |
| TROLAMINE (UNII: 9O3K93S3TK) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| ETHYLPARABEN (UNII: 14255EXE39) |
| CHLORPHENESIN (UNII: I670DAL4SZ) |
| CETYL ALCOHOL (UNII: 936JST6JCN) |
| CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36) |
| METHYLPARABEN (UNII: A2I8C7HI9T) |
| XANTHAN GUM (UNII: TTV12P4NEE) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0299-4930-02 | 1 in 1 CARTON | 01/01/2012 | |
| 1 | | 50 mL in 1 TUBE; 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 | 01/01/2012 | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| G Production Inc. | | 251676961 | manufacture(0299-4930) |