

CETAPHIL HYDRATING FACE SUNSCREEN SPF 35- avobenzone, homosalate, octisalate, octocrylene lotion
Galderma Laboratories, L.P.

Drug Fact

Active Ingredients

Avobenzone 2.8%Sunscreen
Homosalate 9.5%Sunscreen
Octisalate 4.8%Sunscreen
Octocrylene 7%Sunscreen

OTC - PURPOSE SECTION

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
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- 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
- may stain or damage some fabrics

Inactive Ingredients

Water, Glycerin, Dipropylene Glycol, Panthenol (Vitamin B5), Ethylhexyl Methoxycrylene, Isopropyl Palmitate, Silica, Niacinamide, Cetearyl Oliviate, Cetearyl Alcohol, Glyceryl Stearate, Potassium Cetyl Phosphate, Sorbitan Oliviate, Tocopheryl Acetate (Vitamin E Acetate), Caprylyl Glycol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Palmitic Acid, Ethylhexylglycerin, Stearic Acid, Leontopodium Alpinum Flower/Leaf Extract, 1,2-Hexanediol, Oryza Saliva (Rice) Lees Extract, Propanediol, Sodium Hydroxide, Adenosine, Citric Acid, Myristic Acid, Tocopherol (Vitamin E), Buddleja Davidii (Summer Lilac) Leaf Extract, Thymus Vulgaris (Thyme) Leaf Extract

Questions or comments?

1-866-735-4137

Principal Display Panel - 3 FL OZ Carton



NEW

DERMATOLOGIST RECOMMENDED FOR SENSITIVE SKIN



SUN 35

Hydrating Face Sunscreen Broad Spectrum SPF 35

Formulated for sensitive skin Oil-free, lightweight sunscreen hydrates and protects against sun damage

Antioxidant Vitamins B3 and E plus Vitamin B5



3 FL OZ (88 mL)

Cetaphil Hydrating Face Sunscreen BROAD SPECTRUM SPF 35

Lightweight lotion - boosted with Edelweiss Flower Extract, Antioxidant Vitamins B3 and E plus Vitamin B5 - nourishes skin for lasting, 24-hour hydration that strengthens the skin barrier and prevents surface free radical damage.

Trusted by Dermatologists for 75 Years



Defends against 5 Signs of Skin Sensitivity

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

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SPECIFICALLY FORMULATED FOR SENSITIVE SKIN

Drug Facts

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Homosalate 9.5%	Sunscreen
Octisalate 4.8%	Sunscreen
Octocrylene 7%	Sunscreen

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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 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

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Questions or comments? 1-866-735-4137



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WON'T CLOG PORES

PARABEN AND OIL-FREE

FRAGRANCE FREE

OXYBENZONE AND OCTINOXATE FREE

HYPOALLERGENIC

ACTUAL SIZE

LOT:
EXP:

NEW

DERMATOLOGIST RECOMMENDED
FOR SENSITIVE SKIN

Cetaphil®

SUN
35

Hydrating Face
Sunscreen
Broad Spectrum SPF 35

Formulated for sensitive skin

Oil-free, lightweight
sunscreen hydrates and
protects against
sun damage

Antioxidant Vitamins B3 and E
plus Vitamin B5

Skin Cancer Foundation logo

3 FL OZ (88 mL)

Distributed by:

Galderma Laboratories, L.P.

Dallas, Texas 75201 USA

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cetaphil.com

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CETAPHIL HYDRATING FACE SUNSCREEN SPF 35

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0299-4142
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	28 mg in 1 mL
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	95 mg in 1 mL
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	48 mg in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	70 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
Dipropylene Glycol (UNII: E107L85C40)	
Panthenol (UNII: VW9CM0O67Z)	
Ethylhexyl Methoxycrylene (UNII: S3KFG6Q5X8)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Niacinamide (UNII: 25X51I8RD4)	
Cetearyl Olivat (UNII: 58B69Q84JO)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Sorbitan Olivat (UNII: MDL271E3GR)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Carbomer Interpolymer Type A (Allyl Sucrose Crosslinked) (UNII: 59TL3WG5CO)	
Palmitic Acid (UNII: 2V16EO95H1)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Leontopodium Nivale Subsp. Alpinum Flowering Top (UNII: QQC1AK06RK)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
Rice Germ (UNII: 7N2B70SFEZ)	
Propanediol (UNII: 5965N8W85T)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Adenosine (UNII: K72T3FS567)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Myristic Acid (UNII: 0I3V7S25AW)	
Tocopherol (UNII: R0ZB2556P8)	
Buddleja Davidii Leaf (UNII: X380815D32)	
Thymus Vulgaris Leaf (UNII: GRX3499643)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0299-4142-00	1 in 1 CARTON	11/01/2023	
1		88 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 Drug	M020	11/01/2023	

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

Establishment

Name	Address	ID/FEI	Business Operations
ENGLEWOOD LAB, INC.		172198223	label(0299-4142) , manufacture(0299-4142) , pack(0299-4142)

Revised: 10/2023

Galderma Laboratories, L.P.