CERAVE AM FACIAL MOISTURIZING BROAD SPECTRUM SPF 30 SUNSCREENhomosalate, meradimate, octinoxate, zinc oxide, and octocrylene lotion L'Oreal USA Products, Inc.

Drug Facts

Active ingredients

Homosalate 10%

Meradimate 5%

Octinoxate 5%

Octocrylene 2%

Zinc oxide 6.3%

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

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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
- children under 6 months of age: Ask a doctor

Inactive ingredients

water, niacinamide, cetearyl alcohol, glycerin, dimethicone, behentrimonium methosulfate, ceramide 3, ceramide 6-II, ceramide 1, hyaluronic acid, sodium hydroxide, aluminum starch octenylsuccinate, hydroxyethylcellulose, methylparaben, disodium EDTA, propylparaben, sodium lauroyl lactylate, phytosphingosine, cholesterol, carbomer, xanthan gum

Other information

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

Questions or comments?

Toll-free number 1-888-768-2915

www.CeraVe.com





For Normal to Dry Skin with Sunscreen

CeraVe LLC New York, NY 10001

MVE is a registered trademark of DFB Technology,Ltd

3612620732895



Facial Moisturizing Lotion

with Sunscreen

Broad Spectrum SPF 30

Moisturizes throughout the day & helps restore the protective skin barrier

With 3 essential ceramides, niacinamide & hyaluronic acid

OIL FREE



3 FL OZ (89 mL)

CeraVe AM Facial **Moisturizing Lotion** Developed with dermatologists, its unique formula - with moisturizes throughout the day and helps restore the protective skin barrier.



MVE® Delivery Technology Controlled release for all day hydration



Non-Comedogenic Won't clog pores



InVisibleZ<u>inc</u> Technology Microfine zinc oxide that spreads easily, dries with a clear finish



Fragrance Free To avoid fragrance irritation

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Product Information

HUMAN OTC DRUG Item Code (Source) NDC:49967-015 **Product Type**

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	100 mg in 1 mL		
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	50 mg in 1 mL		
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	50 mg in 1 mL		
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	20 mg in 1 mL		
Zinc oxide (UNII: SOI2LOH54Z) (Zinc oxide - UNII:SOI2LOH54Z)	Zinc oxide	63 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
NIACINAMIDE (UNII: 25X5118RD4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
HYALURONIC ACID (UNII: S270N0TRQY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0O6294)	
HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:49967- 015-01	1 in 1 CARTON	08/03/2017		
1		89 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
2	NDC:49967- 015-02	1 in 1 CARTON	08/03/2017		
2		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			
3	NDC:49967- 015-03	5 mL in 1 TUBE; Type 0: Not a Combination Product	08/03/2017		
Л	NDC:49967-	1.5 mL in 1 PACKET; Type 0: Not a Combination	NQ/NQ/2017		

4	015-04	Product	U0/U3/ZU1/	
5	NDC:49967- 015-05	1 in 1 CARTON	08/03/2017	
5		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:49967- 015-06	1 in 1 CARTON	08/03/2017	
6		148 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information					
Marketing Application Number or Monograph Marketing Start Marketing Er Category Citation Date Date					
OTC Monograph Drug	M020	08/03/2017			

Labeler - L'Oreal USA Products, Inc. (002136794)

Establishment				
Name	Address	ID/FEI	Business Operations	
L'Oreal USA Products, Inc.		624244349	MANUFACTURE(49967-015), pack(49967-015)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Universal Packaging Systems, Inc.		078717086	pack(49967-015)	

Revised: 12/2023 L'Oreal USA Products, Inc.