

**CERAVE AM FACIAL MOISTURIZING BROAD SPECTRUM SPF 50 SUNSCREEN-**  
**homosalate, octisalate, octocrylene and zinc oxide lotion**  
**L'Oreal USA Products Inc**

-----

**Drug Facts**

**Active ingredients**

Homosalate 8%

Octisalate 5%

Octocrylene 5%

Zinc oxide 7%

**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 our 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

## Other information

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

## Inactive ingredients

water, glycerin, dimethicone, propanediol, butyloctyl salicylate, steareth-20, cellulose, niacinamide, ethylhexyl methoxycrylene, steareth-2, ceramide NP, ceramide AP, ceramide EOP, sorbitan isostearate, carbomer, glycine soja (soybean) oil, triethoxycaprylsilane, cetearyl alcohol, behentrimonium methosulfate, triethyl citrate, sodium hyaluronate, sodium lauryl lactylate, cholesterol, ammonium polyacryloyldimethyl taurate, tocopherol, chlorphenesin, hydroxyacetophenone, caprylyl glycol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, trisodium ethylenediamine disuccinate, phytosphingosine, xanthan gum, polyhydrostearic acid, polysorbate 60, oryza sativa (rice) bran wax, benzoic acid, c12-22 alkyl acrylate/hydroxyethylacrylate copolymer

## Question or comments?

Toll-free number **1-877-768-2915**

## ***Drug Facts***

### ***Active ingredients***

### ***Purpose***

Homosalate 8% .....	Sunscreen
Octisalate 5% .....	Sunscreen
Octocrylene 5% .....	Sunscreen
Zinc oxide 7%.....	Sunscreen

### ***Uses***

- helps prevent sunburn

- 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

## **Other information**

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

## **Inactive ingredients**

water, glycerin, dimethicone, propanediol, butyloctyl salicylate, steareth-20, cellulose, niacinamide, ethylhexyl methoxycrylene, steareth-2, ceramide NP, ceramide AP, ceramide EOP, sorbitan isostearate, carbomer, glycine soja (soybean) oil, triethoxycaprylylsilane, cetearyl alcohol, behentrimonium methosulfate, triethyl citrate, sodium hyaluronate, sodium lauroyl lactylate, cholesterol, ammonium polyacryloyldimethyl taurate, tocopherol, chlorphenesin, hydroxyacetophenone, caprylyl glycol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, trisodium ethylenediamine disuccinate. phytosphingosine. xanthan gum.



polyhydroxystearic acid, polysorbate 60, oryza sativa (rice) bran wax, benzoic acid, C12-22 alkyl acrylate/hydroxyethylacrylate copolymer

## Questions or comments?

Toll-free number **1-888-768-2915**

2069507 25 (CODE F.I.L. V70040857/1)



## Drug Facts

### Active ingredients

### Purpose

Homosalate 8% .....	Sunscreen
Octisalate 5% .....	Sunscreen
Octocrylene 5% .....	Sunscreen
Zinc oxide 7% .....	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.

**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

## ***Other information***

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

## ***Inactive ingredients***

water, glycerin, dimethicone, propanediol, butyloctyl salicylate, steareth-20, cellulose, niacinamide, ethylhexyl methoxycrylene, steareth-2, ceramide NP, ceramide AP, ceramide EOP, sorbitan isostearate, carbomer, glycine soja (soybean) oil, triethoxycaprylylsilane, cetearyl alcohol, behentrimonium methosulfate, triethyl citrate, sodium hyaluronate, sodium lauroyl lactylate, cholesterol, ammonium polyacryloyldimethyl taurate, tocopherol, chlorphenesin, hydroxyacetophenone, caprylyl glycol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, trisodium ethylenediamine disuccinate, phytosphingosine, xanthan gum, polyhydroxystearic acid, polysorbate 60, oryza sativa (rice) bran wax, benzoic acid, C12-22 alkyl acrylate/hydroxyethylacrylate copolymer

## ***Questions or comments?***

Toll-free number **1-888-768-2915**

2069507 25 (CODE F.I.L. V70040857/1)







## ***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
Homosalate 8% .....	Sunscreen
Octisalate 5% .....	Sunscreen
Octocrylene 5% .....	Sunscreen
Zinc oxide 7%.....	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

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

### ***Other information***

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

### ***Inactive ingredients***

water, glycerin, dimethicone, propanediol, butyloctyl salicylate, steareth-20, cellulose, niacinamide, ethylhexyl methoxycrylene, steareth-2, ceramide NP, ceramide AP, ceramide EOP, sorbitan isostearate, carbomer, glycine soja (soybean) oil, triethoxycaprylylsilane, cetearyl alcohol, behentrimonium methosulfate, triethyl citrate, sodium hyaluronate, sodium lauroyl lactylate, cholesterol, ammonium polyacryloyldimethyl taurate, tocopherol, chlorphenesin, hydroxyacetophenone, caprylyl glycol, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, trisodium ethylenediamine disuccinate, phytosphingosine, xanthan gum, polyhydroxystearic acid, polysorbate 60, oryza sativa (rice) bran wax, benzoic acid, C12-22 alkyl acrylate/hydroxyethylacrylate copolymer

### ***Questions or comments?***

Toll-free number **1-888-768-2915**

2069507 25 (CODE F.I.L. V70040857/1)





**NEW SPF 50**

**CeraVe<sup>®</sup>**

DEVELOPED WITH DERMATOLOGISTS



**Facial  
Moisturizing  
Lotion**

**50**

with Sunscreen

**Broad Spectrum  
SPF 50**

**Moisturizes throughout the  
day & helps restore the  
protective skin barrier**



PROTECTIVE SKIN BARRIER

With 3 essential ceramides,  
niacinamide & hyaluronic acid

**LIGHTWEIGHT**

3 FL OZ (89 ml)



**NEW SPF 50**

**CeraVe<sup>®</sup>**

DEVELOPED WITH DERMATOLOGISTS



# Facial Moisturizing Lotion

with Sunscreen

# 50

**Broad Spectrum  
SPF 50**

**Moisturizes throughout the  
day & helps restore the  
protective skin barrier**

With 3 essential ceramides,  
niacinamide & hyaluronic acid

**LIGHTWEIGHT**

**3 FL OZ (89 ml)**





**NEW SPF 50**

**CeraVe<sup>®</sup>**

DEVELOPED WITH DERMATOLOGISTS



**Facial  
Moisturizing  
Lotion**

**50**

with Sunscreen

**Broad Spectrum  
SPF 50**

**Moisturizes throughout the day & helps restore the protective skin barrier**

With 3 essential ceramides, niacinamide & hyaluronic acid

**LIGHTWEIGHT**

**3 FL OZ (89 ml)**







CeraVe® AM Facial  
Moisturizing Lotion

**Drug Facts:**

**Active ingredients:** Homosalate 8%, Octisalate 5%, Octocrylene 5%, Zinc oxide 7% **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. **Other information:** Protect the product in this container from excessive heat and direct sun. **Questions or comments? 1-888-768-2915**

CeraVe LLC, New York, NY 10001, Made in USA of US  
and/or Imported Ingredients, [www.cerave.com](http://www.cerave.com)

2069507 25 (CODE F.I.L. V70040857/1)  
3612624094661



CeraVe® AM Facial  
Moisturizing Lotion



## Drug Facts:

**Active ingredients:** Homosalate 8%, Octisalate 5%, Octocrylene 5%, Zinc oxide 7%

**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. **Other information:** Protect the product in this container from excessive heat and direct sun. **Questions or comments? 1-888-768-2915**

CeraVe LLC, New York, NY 10001, Made in USA of US and/or Imported Ingredients, [www.cerave.com](http://www.cerave.com)

2069507 25 (CODE F.I.L. V70040857/1)  
3612624094661



CeraVe® AM Facial  
Moisturizing Lotion

**Drug Facts:**

**Active ingredients:** Homosalate 8%, Octisalate 5%, Octocrylene 5%, Zinc oxide 7% **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



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. **Other information:** Protect the product in this container from excessive heat and direct sun. **Questions or comments? 1-888-768-2915**

CeraVe LLC, New York, NY 10001, Made in USA of US and/or Imported Ingredients, [www.cerave.com](http://www.cerave.com)

2069507 25 (CODE F.I.L. V70040857/1)  
3612624094661



**CeraVe**<sup>®</sup>

DEVELOPED WITH DERMATOLOGISTS



**Facial  
Moisturizing  
Lotion** **50**

with Sunscreen

**Broad Spectrum  
SPF 50**

**Moisturizes throughout the  
day & helps restore the  
protective skin barrier**

With 3 essential ceramides,  
niacinamide & hyaluronic acid

**LIGHTWEIGHT**

**3 FL OZ (89 mL)**

3612624094692



**CeraVe**<sup>®</sup>  
DEVELOPED WITH DERMATOLOGISTS

 **AM**

**Facial  
Moisturizing  
Lotion** **50**  
with Sunscreen

**Broad Spectrum  
SPF 50**

Moisturizes throughout the  
day & helps restore the  
protective skin barrier

With 3 essential ceramides,  
niacinamide & hyaluronic acid

**LIGHTWEIGHT**

3.5 FL OZ (100 mL)







## CERAVE AM FACIAL MOISTURIZING BROAD SPECTRUM SPF 50 SUNSCREEN

homosalate, octisalate, octocrylene and zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49967-263
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	80 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	50 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	70 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>STEARETH-20</b> (UNII: L0Q8IK9E08)	
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>ETHYLHEXYL METHOXYCRYLENE</b> (UNII: S3KFG6Q5X8)	
<b>STEARETH-2</b> (UNII: V56DFE46J5)	

<b>CERAMIDE NP</b> (UNII: 4370DF050B)
<b>CERAMIDE AP</b> (UNII: F1X8L2B00J)
<b>CERAMIDE 1</b> (UNII: 5THT33P7X7)
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>BEHENTRIMONIUM METHOSULFATE</b> (UNII: 5SHP745C61)
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>SODIUM LAUROYL LACTYLATE</b> (UNII: 7243K85WFO)
<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)
<b>AMMONIUM POLYACRYLOYLDIMETHYL TAURATE</b> (UNII: F01RIY4371)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)</b> (UNII: 86FQE96TZ4)
<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)
<b>PHYTOSPHINGOSINE</b> (UNII: GIN46U9Q2Q)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>POLYHYDROXYSTEARIC ACID STEARATE</b> (UNII: 8KQ7I65XZE)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>RICE BRAN</b> (UNII: R60QEP13IC)
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-263-01	1 in 1 CARTON	07/01/2024	
1		89 mL in 1 PACKAGE; 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	07/01/2024	

**Labeler** - L'Oreal USA Products Inc (002136794)

## Establishment

Name	Address	ID/FEI	Business Operations
L'OREAL USA PRODUCTS, INC		624244349	manufacture(49967-263)



