#### CERAVE DEVELOPED WITH DERMOTOLOGISTS ULTRA LIGHT MOISTURIZING BROAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate and octocrylene lotion L'Oreal USA Products Inc

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#### **Drug Facts**

#### **Active ingredients**

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.7%

### 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 hear and direct sun

## Inactive ingredient

water, C12-15 alkyl benzoate, glyceryl stearate SE, methyl methacrylate crosspolymer, glycerin, pentylene glycol, ceramide NP (ceramide 3), ceramide AP (ceramide 6-II), ceramide EOP (ceramide 1), phytosphingosine, sodium acryloyldimethyltaurate/VP crosspolymer, sodium lauroyl lactylate, cholesterol, xanthan gum, carbomer, hydroxyacetophenone, disodium EDTA, citric acid, sodium hyaluronate

# **Questions or comments?**

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





C1 - Internal use

avobenzone, homosalate, oc	isuate and betoerylene h				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC		:49967-517	
Route of Administration	TOPICAL				
Active Ingredient/Active	Moiety				
Ingree	dient Name		<b>Basis of Stren</b>	gth	Strength
AVOBENZONE (UNII: G63QQF2NO	X) (AVOBENZONE - UNII:G63QC	QF2NOX)	AVOBENZ ONE		30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S	) (HOMOSALATE - UNII:V06SV4	M95S)	HOMOSALATE		100 mg in 1 m
OCTISALATE (UNII: 4X49Y0596W)	(OCTISALATE - UNII:4X49Y0596	5W)	OCTISALATE		50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6V	M) (OCTOCRYLENE - UNII:5A68	BWGF6WM)	OCTOCRYLENE		27 mg in 1 mL
Inactive Ingredients					
	Ingredient Name				Strength
WATER (UNII: 059QF0KO0R)					
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)					
GLYCERYL STEARATE SE (UNII: F	CZ5MH785I)				
GLYCERIN (UNII: PDC6A3C0OX)					
PENTYLENE GLYCOL (UNII: 50C1307PZG)					
CERAMIDE NP (UNII: 4370DF050B)					
CERAMIDE AP (UNII: F1X8L2B00J)					
CERAMIDE 1 (UNII: 5THT33P7X7)					
PHYTOSPHINGOSINE (UNII: GIN4)					
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO) CHOLESTEROL (UNII: 97C5T2UQ7])					
XANTHAN GUM (UNII: TTV12P4NEI					
CARBOXYPOLYMETHYLENE (UNI					
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)					
EDETATE DISODIUM (UNII: 7FLD91C86K)					
CITRIC ACID MONOHYDRATE (UI					

P	Packaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-517- 01	1 in 1 CARTON	01/22/2018	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-517- 02	5 mL in 1 TUBE; Type 0: Not a Combination Product	01/22/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	01/22/2018		

Labeler - L'Oreal USA Products Inc (002136794)

# Establishment

Name	Address	ID/FEI	Business Operations
Accupac, LLC		061595175	manufacture(49967-517) , pack(49967-517)

Revised: 12/2023

L'Oreal USA Products Inc