

GARNIER OMBRELLE SPF 60 FACE ULTRA LIGHT- octocrylene, titanium dioxide, avobenzone, drometrizole trisiloxane and terephthalylidene dicamphor sulfonic acid lotion
L'Oreal USA Products Inc

Drug Facts

Active ingredients

Octocrylene 10%

Titanium Dioxide 4.15%

Avobenzone 3.5%

Drometrizole Trisiloxane 3%

Terephthalylidene Dicamphor Sulfonic Acid 3%

Caution

For external use only. Discontinue use if skin irritation develops or increases. If irritation persists, consult a doctor. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Keep out of reach of children. Before use on children under 6 months, consult a doctor. Do not expose babies and young children directly to the sun. Avoid contact with textiles.

Directions

Apply generously 15 to 30 minutes before sun exposure. Reapply at least every 2 hours or after swimming, washing, towel drying or perspiring heavily.

Others

Aqua, Propylene Glycol, Glycerin, Cyclopentasiloxane, Triethanolamine, Isopropyl Palmitate, Stearic Acid, VP/Eicosene Copolymer, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aluminum Hydroxide, Carbomer, Disodium EDTA, Glyceryl Stearate, Glycine Soja, Hydroxypropyl Methylcellulose, Methylparaben, PEG-100 Stearate, Phenoxyethanol, Propylparaben, Stearyl alcohol, Tocopherol

**PROTECTION UVA-UVB
À LARGE SPECTRE BREVETÉE
AVEC TECHNOLOGIE MEXORYL®***

Le système filtrant breveté de Ombrelle® avec la technologie Mexoryl® et autres filtres solaires procure une protection UVA/UVB à large spectre efficace.

BÉNÉFICES

- Ombrelle® Crème Visage FPS 60, contenant la vitamine E revitalisante comme antioxydant**, est conçue spécialement pour la peau délicate du visage.
- Sa texture légère est développée pour une sensation de confort à l'application et un toucher non gras. Texture idéale pour les peaux normales à sèches.
- Elle s'absorbe rapidement et n'obstrue pas les pores.
- Cette formule hydratante aide à prévenir l'apparence des signes du vieillissement de la peau et peut être utilisée chaque jour.
- Cette crème hypoallergénique est non comédogène et ne contient ni parfum ni colorant.
- Les écrans solaires que contient ce produit répondent aux critères établis par l'Association canadienne de dermatologie.

MODE D'EMPLOI

Appliquer généreusement 15 à 30 minutes avant l'exposition au soleil. Appliquer de nouveau le produit au moins toutes les 2 heures, après la baignade, le bain, le séchage à la serviette ou après avoir transpiré abondamment.

MISE EN GARDE

Pour usage externe seulement. Cesser d'utiliser si une irritation de la peau se développe ou devient plus sévère. Si l'irritation persiste, consulter un médecin. Éviter tout contact avec les yeux. En cas de contact, rincer abondamment avec de l'eau. Tenir hors de la portée des enfants. Avant d'utiliser sur un enfant de moins de 6 mois, consulter un médecin. Ne pas exposer les bébés et les jeunes enfants directement au soleil. Éviter le contact avec les textiles.

GARNIER®

Pionnier de la protection solaire depuis 1936.

www.ombrelle.ca
1 888 9-OMBREL

Mexoryl® is a registered trademark /
est une marque de commerce déposée de L'Oréal S.A.
imp. by / par Ombrelle Canada, Montreal H4T 1K5

* Avec technologie Mexoryl® et autres filtres solaires. K9542303
** Ingrédients cosmétiques : vitamine E (Tocophérol) 2048365

**PATENTED BROAD-SPECTRUM
UVA-UVB PROTECTION WITH
MEXORYL® TECHNOLOGY**

Ombrelle®'s patented filtering system with Mexoryl® technology and other sunscreen filters provides effective broad-spectrum UVA/UVB protection.

BENEFITS

- Ombrelle® Face Cream SPF 60 contains revitalizing vitamin E antioxidant** and is specifically formulated for the delicate skin of the face.
- Its light texture is developed for a comfortable application and a non-greasy finish. Ideal texture for normal to dry skin.
- It absorbs quickly and does not clog pores.
- This moisturizing formula helps prevent the appearance of skin aging signs and can be used every day.
- This hypoallergenic cream is non-comedogenic, fragrance and colorant free.
- The sunscreens in this product meet the criteria established by the Canadian Dermatology Association.

DIRECTIONS

Apply generously 15 to 30 minutes before sun exposure. Reapply at least every 2 hours, or after swimming, washing, towel drying or perspiring heavily.

CAUTION

For external use only. Discontinue use if skin irritation develops or increases. If irritation persists, consult a doctor. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Keep out of reach of children. Before use on children under 6 months, consult a doctor. Do not expose babies and young children directly to the sun. Avoid contact with textiles.

GARNIER®

Sun protection pioneer since 1936.

**292591/2 - Active
Ingredients Actifs (w/w):**

Octocrylene: 10%, Titanium Dioxide: 4.15%, Avobenzone: 3.5%,
Drometrizole Trisiloxane (Mexoryl® XL): 3%, Terephthalidene
Dicamphor Sulfonic Acid (Mexoryl® SX): 3%.

Others/Autres:

Aqua, Propylene Glycol, Glycerin, Cyclopentasiloxane, Triethanolamine,
Isopropyl Palmitate, Stearic Acid, VP/Eicosene Copolymer,
Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer,
Aluminum Hydroxide, Carbomer, Disodium EDTA, Glyceryl Stearate,
Bis(4-Ethylphenyl) Sulfone, Hydroxypropyl Methylcellulose, Methylparaben,
PEG-100 Stearate, Phenoxethanol, Propylparaben, Stearyl
Alcohol, Tocopherol. Code F.I.L.: K44121/2

* With Mexoryl® technology and other sunscreen filters.
** Cosmetic ingredient: vitamin E (Tocopherol)

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-813
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	41.5 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	35 mg in 1 mL	
DROMETRIZOLE TRISILOXANE (UNII: HC228451IX) (DROMETRIZOLE TRISILOXANE - UNII:HC228451IX)	DROMETRIZOLE TRISILOXANE	30 mg in 1 mL	

ECAMSULE (UNII: M94R1PM439) (ECAMSULE - UNII:M94R1PM439)	ECAMSULE	50 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SOYBEAN OIL (UNII: 241ATL177A)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-813-01	75 mL in 1 TUBE; Type 0: Not a Combination Product	10/10/2011	
2	NDC:49967-813-02	6 mL in 1 TUBE; Type 0: Not a Combination Product	10/30/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
export only		10/10/2011	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
L'OREAL USA, INC		624244349	manufacture(49967-813)