

GARNIER OMBRELLE SPF 30 FACE ULTRA LIGHT- octocrylene, drometrizole trisiloxane, avobenzone, titanium dioxide and terephthalylidene dicamphor sulfonic acid cream
L'Oreal USA Products Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients

Octocrylene 5%

Drometrizole Trisiloxane 4%

Avobenzone 3%

Titanium Dioxide 2.9%

Terephthalylidene Dicamphor Sulfonic Acid 1%

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, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Glycerin, Pentylene Glycol, Stearic Acid, Triethanolamine, Potassium Cetyl Phosphate, Propylene Glycol, Panthenol, PEG-100 Stearate, Glyceryl Stearate, Phenoxyethanol, Cetyl Alcohol, Dimethicone, Methylparaben, Aluminum Hydroxide, Capryly Glycol, Ethylparaben, Carbomer, Tocopherol, Xanthan Gum, Disodium EDTA

**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 30, contenant la vitamine E revitalisante comme antioxydant** et la vitamine B5 revitalisante, est conçue spécialement pour la peau délicate du visage.
- Sa texture ultra 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.

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. par / par Ombrelle Canada, Montreal H4T 1K5

* Avec technologie Mexoryl® et autres filtres solaires. K9542903
** Ingrédient cosmétique : vitamine E (tocophérol) 2048341



**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 30 contains revitalizing vitamins E antioxidant** and B5 and is specifically formulated for the delicate skin of the face.
- Its ultra-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.

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.

**737099/2 – Active
Ingredients Actifs (w/w):**

Octocrylene: 5%, Drometrizole Trisiloxane (Mexoryl® XL): 4%, Avobenzone: 3%, Titanium Dioxide: 2.9%, Terephthalylidene Dicamphor Sulfonic Acid (Mexoryl® SX): 1%.

Others/Autres:

Aqua, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Glycerin, Pentylene Glycol, Stearic Acid, Triethanolamine, Potassium Cetyl Phosphate, Propylene Glycol, Panthenol, PEG-100 Stearate, Glyceryl Stearate, Phenylethanol, Cetyl Alcohol, Dimethicone, Methylparaben, Aluminum Hydroxide, Caprylyl Glycol, Ethylparaben, Carbomer, Tocopherol, Xanthan Gum, Disodium EDTA. Code F.I.L.: K44127/2

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



GARNIER OMBRELLE SPF 30 FACE ULTRA LIGHT

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-162
Route of Administration	TOPICAL		

Active Ingredient/Active Moieity

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL
DROMETRIZOLE TRISILOXANE (UNII: HC228451IX) (DROMETRIZOLE TRISILOXANE - UNII:HC228451IX)	DROMETRIZOLE TRISILOXANE	40 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	29 mg in 1 mL
ECAMSIII E (UNII: M04P1DM439) (ECAMSIII E - UNII:M04P1DM439)	ECAMSIII E	10 mg

EXAMPLE (UNII: M34R1F433) (EXAMPLE - UNII:M34R1F433)	EXAMPLE	in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PANTHENOL (UNII: WV9CM0O67Z)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYL PARABEN (UNII: 14255EXE39)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-162-01	75 mL in 1 TUBE; Type 0: Not a Combination Product	10/10/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/10/2011	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
L'OREAL USA, INC		624244349	manufacture(49967-162)