

LAURA MERCIER TINTED MOISTURIZER BROAD SPECTRUM SPF 20 SUNSCREEN - NUDE- meradimate, octinoxate cream
Gurwitch Products, L.L.C.

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.

Laura Mercier Tinted Moisturizer Broad Spectrum SPF 20 Sunscreen - Nude

Drug Facts

Active Ingredients

Meradimate (3.5%)

Octinoxate (7.5%)

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decrease 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
- use a water-resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- 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 AM to 2 PM.
- wear long-sleeved shirts, pants, hats and sunglasses
- children under 6 months: Ask a doctor.

Other information:

- protect this product from excessive heat and direct sun.

Inactive ingredients

water, cetearyl alcohol, peg-40 castor oil, dimethicone, polyglyceryl-4 isostearate, cyclomethicone, dea-cetyl phosphate, hexyl laurate, emu oil, tocopheryl acetate, cetyl peg/ppg-10/1 dimethicone, polysorbate 60, diazolidinyl urea, magnesium aluminum silicate, sodium ascorbate, propylparaben. may contain: iron oxides, titanium dioxide, mica

Questions or comments?

Call 1-888-637-2437, M - F 9am - 5pm CST.

Product Label

NUDE
TINTED MOISTURIZER
BROAD SPECTRUM SPF 20 SUNSCREEN
LIGHTWEIGHT FLAWLESS COVERAGE

Laura Mercier's Tinted Moisturizer is a perfect blend of skincare and makeup. This lightweight formula hydrates skin and softens fine lines with a sheer hint of colour for a healthy, dewy glow. It protects with Broad Spectrum SPF 20 Sunscreen. Perfect for all skin types.

The Technique: Apply to clean skin with Laura's foundation sponge or with fingertips.

DERMATOLOGIST TESTED. NON COMEDOGENIC.

Drug Facts (continued)
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, cetearyl alcohol, PEG-40 castor oil, dimethicone, polyglyceryl-4 isostearate, cyclomethicone, dea-cetyl phosphate, hexyl laurate, emu oil, tocopheryl acetate, cetyl PEG/PPG-10/1 dimethicone, polysorbate 60, diazolidinyl urea, sodium dehydroacetate, sodium hyaluronate, allantoin, carbomer, methylparaben, magnesium aluminum silicate, sodium ascorbate, propylparaben. may contain: iron oxides, titanium dioxide, mica.

Questions or comments?
Call 1-888-637-2437, M – F 9am – 5pm CST.

laura mercier
NOT FOR RESALE
NET, GURWITCH PRODUCTS, L.L.C.
PO BOX 7568, NEW YORK, NY 10150
MADE IN USA. lauramercier.com

Drug Facts

Active Ingredients	Purpose
Meradimate 3.5%	Sunscreen
Octinoxate 7.5%	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
• use a water resistant sunscreen if swimming or sweating
• reapply at least every 2 hours
• **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

7 386150 11330 6

4-COLOR
FINAL PHOTO
FPO

TINTED MOISTURIZER
BROAD SPECTRUM SPF 20 SUNSCREEN
LIGHTWEIGHT FLAWLESS COVERAGE

NET WT. 0.07 OZ./2 g

◀ FOR FULL DRUG FACTS OPEN HERE

LAURA MERCIER TINTED MOISTURIZER BROAD SPECTRUM SPF 20 SUNSCREEN - NUDE

meradimate, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65342-1403
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	35 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
EMU OIL (UNII: 344821WD61)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
SODIUM ASCORBATE (UNII: S033EH8359)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65342-1403-0	2 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/09/2015	

Labeler - Gurwitch Products, L.L.C. (884875246)

Establishment

Name	Address	ID/FEI	Business Operations
Qualis Packaging		078387992	pack(65342-1403)

Revised: 7/2015

Gurwitch Products, L.L.C.