

**LAURA MERCIER TINTED MOISTURIZER BROAD SPECTRUM SPF 20 SUNSCREEN
WALNUT- meradimate, octinoxate cream
Gurwitch Products, LLC**

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 Walnut

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), 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 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.

Package Labeling:



laura mercier[®]
 DIST. GURWITCH PRODUCTS, L.L.C.,
 PO BOX 7568,
 NEW YORK, NY 10150
 MADE IN USA lauramercier.com 001

Drug Facts (continued)

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

1.7 FL.OZ./50 ml

laura mercier

tinted moisturizer
 BROAD SPECTRUM SPF 20 SUNSCREEN
 LIGHTWEIGHT FLAWLESS COVERAGE

Drug Facts

Active ingredients

Meradimate 3.5%
 Octinoxate 7.5%

Purpose

Sunscreen
 Sunscreen

Uses • helps prevent sunburn

Drug Facts (continued)

• 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.

Drug Facts (continued)

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

Drug Facts (continued)

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.

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tinted moisturizer

BROAD SPECTRUM SPF 20 SUNSCREEN
LIGHTWEIGHT FLAWLESS COVERAGE

laura mercier

LAURA MERCIER'S TINTED MOISTURIZER IS A PERFECT BLEND OF SKINCARE AND MAKEUP. IT HYDRATES SKIN, AND SOFTENS FINE LINES WITH A SHEER HINT OF COLOUR FOR A HEALTHY, DEWY GLOW. THIS LIGHTWEIGHT FORMULA PROVIDES IDEAL PROTECTION FROM THE SUN'S HARMFUL, DAMAGING RAYS WITH BROAD SPECTRUM UVB/UVA SUNSCREEN. PERFECT FOR ALL SKIN TYPES.

The Technique: Apply to clean skin with Laura's foundation sponge or with fingertips. Layer for additional coverage. DERMATOLOGIST TESTED, NON COMEDOGENIC.

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.

Active ingredients: Meradimate: 3.5%, Octinoxate: 7.5%

laura mercier®

DIST. GURWITCH PRODUCTS, L.L.C.
PO BOX 7568, NEW YORK, NY 10150

MADE IN USA

lauramercier.com

001

1.7 FL.OZ./50 ml

WALNUT

LAURA MERCIER TINTED MOISTURIZER BROAD SPECTRUM SPF 20 SUNSCREEN WALNUT

meradimate, octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65342-7600
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 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

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)
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
ALLANTOIN (UNII: 344S277G0Z)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
METHYL PARABEN (UNII: A2I8C7HI9T)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
SODIUM ASCORBATE (UNII: S033EH8359)
PROPYL PARABEN (UNII: Z8IX2SC1OH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65342-7600-1	1 in 1 CARTON	01/05/2017	
1		50 mL in 1 TUBE; 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	01/05/2017	

Labeler - Gurwitch Products, LLC (884875246)