

**CETAPHIL SUN TINTED FACE SPF 40- titanium dioxide, zinc oxide lotion**  
**Galderma Laboratories, L.P.**

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**Drug Facts**

**Active Ingredients**

Titanium Dioxide 10.1%  
Zinc Oxide 7.8 %

**Purpose**

Sunscreen

**Use(s)**

- 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.**

**Stop use and ask a doctor if rash occurs.**

**When using this product, keep out of eyes.**

Rinse with water to remove.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply liberally 15 minutes before sun exposure.
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours.
- Children under 6 months: ask a doctor

**SUN PROTECTION MEASURES:** Spending time in the sun increases your risk of 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 10am - 2 pm.
- Wear long-sleeved shirts, pants, hats, and sun glasses.

**Other Information**

- Protect this product from excessive heat and direct sun.

### **Inactive Ingredients**

ALLANTOIN, BENZYL ALCOHOL, C12-15 ALKYL BENZOATE, CAFFEINE, CAPRYLYL METHICONE, CETYL DIGLYCERYL TRIS(TRIMETHYLSILOXY) SILYLETHYL DIMETHICONE, CHROMIUM OXIDE GREENS, DICAPRYLYL CARBONATE, DIMETHICONE, DIPOTASSIUM GLYCYRRHIZATE, ETHYLHEXYLGLYCERIN, GLYCERIN, HYDROGENATED LECITHIN, IRON OXIDES, ISOHEXADECANE, MAGNESIUM SULFATE, MEHYLPROPANEDIOL, SILICA, TOCOPHEROL, TRIETHOXYCAPRYLYLSILANE, TRISILOXANE, WATER

### **Questions?**

1-866-735-4137

**PRINCIPAL DISPLAY PANEL - 1.7 FL OZ (50 mL) carton**



NEW



SUN  
40

### Everyday Sunscreen Tinted Face Lotion

Broad Spectrum SPF 40

All Skin Types

Hydrating formula soothes, protects and blends seamlessly with a variety of skin tones

100% Mineral UVA/UVB Filters & Antioxidant Vitamin E

Tinted

### Cetaphil® Everyday Sunscreen Tinted Face Lotion SPF 40

Daily use formula protects against harmful UV rays to help prevent sunburn and decrease the risk of skin cancer and early signs of aging due to sun exposure.

Tinted formula immediately hydrates and helps restore the skin's moisture barrier.

Trusted by Dermatologists  
for 75 Years



Defends against 5 Signs of Skin Sensitivity

- Weakened Skin Barrier
- Dryness
- Irritation
- Roughness
- Tightness

GALDERMA

Distributed by:  
Galderma Laboratories, L.P.  
Dallas, TX 75201 USA

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cetaphil.com



Pump Tube  
1.7 FL OZ (50mL)



Actual Size

#### Drug Facts

**Active Ingredients.... Purpose**  
Titanium Dioxide 10.1% ..... Sunscreen  
Zinc Oxide 7.8% ..... Sunscreen

#### Use(s)

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- 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.**  
**Stop use and ask a doctor if rash occurs.**  
When using this product, keep out of eyes. Rinse with water to remove.  
**Keep out of reach of children.**  
If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- Apply liberally 15 minutes before sun exposure.
  - Use a water resistant sunscreen if swimming or sweating.
  - Reapply at least every 2 hours.
  - Children under 6 months: ask a doctor.
- SUN PROTECTION MEASURES:**  
Spending time in the sun increases your risk of 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 10am-2pm.
  - Wear long-sleeved shirts, pants, hats and sun glasses.

#### Other Information

- Protect this product from excessive heat and direct sun.

**Inactive Ingredients** ALLANTOIN, BENZYL ALCOHOL, C12-15 ALKYL BENZOATE, CAFFEINE, CAPRYLYL METHICONE, CETYL DIGLYCERYL TRIS(Trimethylsiloxy)silyl ethyl dimethicone, CHROMIUM OXIDE GREENS, DICAPRYLYL CARBONATE, DIMETHICONE, DIPOTASSIUM GLUCYRRHIZATE, ETHYLHEXYLGLYCERIN, GLYCERIN, HYDROGENATED LECITHIN, IRON OXIDES, ISOHEXADECANE, MAGNESIUM SULFATE, METHYLPROPANEDIOL, SILICA, TOCOPHEROL, TRIETHOXYCAPRYLYLSILANE, TRISILOXANE, WATER

**Questions?** 1-866-735-4137

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NEW

Cetaphil®

P 57726-0

SUN  
40

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Broad Spectrum SPF 40

All Skin Types

Hydrating formula soothes, protects  
and blends seamlessly with a variety  
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100% Mineral UVA/UVB Filters &  
Antioxidant Vitamin E

Tinted

Pump tube image

National Eczema Association logo

1.7 FL OZ (50 ML)

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cetaphil.com  
P57726-0

### CETAPHIL SUN TINTED FACE SPF 40

titanium dioxide, zinc oxide lotion

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0299-4145
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	101 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	78 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>CHROMIC OXIDE</b> (UNII: X5Z09SU859)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>GLYCYRRHIZINATE DIPOTASSIUM</b> (UNII: CA2Y0FE3FX)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>Magnesium Sulfate, Unspecified Form</b> (UNII: DE08037SAB)	
<b>METHYLPROPANEDIOL</b> (UNII: N8F53B3R4R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>TRISILOXANE</b> (UNII: 9G1ZW13R0G)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0299-4145-00	1 in 1 CARTON	10/31/2024	
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 Drug	M020	10/31/2024	

**Labeler** - Galderma Laboratories, L.P. (047350186)

## Establishment

Name	Address	ID/FEI	Business Operations
Port Jervis Laboratories, Inc		001535103	manufacture(0299-4145)