

VITAMIN C ESTER PHOTO-BRIGHTENING MOISTURIZER BROAD SPECTRUM SPF 30 59ML- titanium dioxide cream

N.V Perricone 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.

<p>Drug Facts</p> <p>Active Ingredient Titanium Dioxide (4.20%) Purpose Sunscreen</p> <p>Uses • Help prevent sunburn. • If used as directed with other sun protection measures (see Directions), decreases the chance of skin cancer and early skin aging caused by exposure to the sun.</p> <p>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 immediately.</p> <p>Directions • Apply to face & neck prior to sun exposure. For best results, apply after your favorite Perricone MD serum, serum concentrate or facial cream.</p>	<p>Drug Facts (Continued)</p> <p>For Sunscreen Use:</p> <ul style="list-style-type: none"> • Apply liberally 15 minutes before sun exposure. • Use a water-resistant sunscreen if swimming or sweating. • Reapply at least every 2 hours. • Not for use on children. • 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: <ul style="list-style-type: none"> • Limit time in the sun, especially from 10 a.m.–2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses. <p>Inactive Ingredients Water/Aqua/Eau, Glycerin, Cyclopentasiloxane, Dimethicon, Pentylen Glycol, Ethylhexyl Methoxycinnamate, Polyester-8, Polyisobutylene, Polydimethylsiloxane, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Benzyl Alcohol, Aluminum Hydroxide, Stearic Acid, Dimethyl Isosorbide/Dimersalate, ▾</p>	<p>VITAMIN C ESTER Photo-Brightening Moisturizer Broad Spectrum SPF 30 Instant hydration & protection against environmental aggressors</p> <p>Perricone MD</p> <p>VITAMIN C ESTER Photo-Brightening Moisturizer Broad Spectrum SPF 30</p> <p>Vitamin C Ester, Alpha Lipoic Acid, Mineral-Based Sunscreen 15 mL / 0.5 fl oz</p>	<p>KEY INGREDIENTS</p> <p>Vitamin C Ester: Supercharged Brightening & Smoothing A more potent, highly stable & less abrasive form of antioxidant-rich vitamin C. Vitamin C Ester gives the appearance of collagen-rich skin by visibly smoothing, brightening & minimizing discoloration over time. Unlike traditional vitamin C, Vitamin C Ester is fat-soluble & easily absorbable for maximum antioxidant benefits.</p> <p>Alpha Lipoic Acid (ALA): Nature's Most Powerful Antioxidant A fatty acid found in every cell in the human body, ALA reduces the appearance of lines, wrinkles & enlarged pores/wrinkles. It's & works well with ALA is highly absorbable & works alongside the body's own antioxidant system.</p> <p>Mineral-Based Sunscreen: Advanced SPF Protection Minerals found deep within the earth are ground into ultra-fine powders that act like a mirror to deflect aging UVA & burning UVB rays & can be less irritating than traditional chemical sunscreens.</p>

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Inactive Ingredients Water/Aqua/Eau, Glycerin, Cyclopentasiloxane, Dimethicon, Pentylen Glycol, Ethylhexyl Methoxycrylene, Polywater B, Polyglyceryl-3 Polydimethylacetyl Dimethicone, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Benzyl Alcohol, Aluminum Hydroxide, Stearic Acid, Dihydroxy Syringylbenzenate, ▼

Lot Code area
Expiration date

Other Information Perricone MD product in this container from Duesseldorf, Germany. ©2009 Perricone MD, Inc. All rights reserved. Perricone MD, the Perricone MD logo, and the Perricone MD color scheme are trademarks of Perricone MD, Inc.

Drug Facts (Continued)

VITAMIN C ESTER
Photo-Brightening Moisturizer
Broad Spectrum SPF 30
Instant hydration & protection against environmental aggressors

Perricone MD

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Photo-Brightening Moisturizer
Broad Spectrum SPF 30
Vitamin C Ester, Alpha Lipoic Acid, Mineral-Based Sunscreen
€ 15 mL / 0.5 fl oz

KEY INGREDIENTS

Vitamin C Ester: Supercharged Brightening & Smoothing A more potent, highly stable & less abrasive form of antioxidant rich vitamin C. Vitamin C Ester gives the appearance of collagen-rich skin by visibly smoothing, brightening & minimizing discoloration over time. Unlike traditional vitamin C, Vitamin C Ester is fat-soluble & easily absorbable for maximum antioxidant benefits.

Alpha Lipoic Acid (ALA): Nature's Most Powerful Antioxidant A fatty acid found in every cell in the human body, ALA reduces the appearance of fine wrinkles & enlarged pores over time. Fat- & water-soluble, ALA is highly absorbable & works alongside the body's own antioxidant system.

Mineral-Based Sunscreen: Advanced SPF Protection Minerals found deep within the earth are ground into ultra-fine powders that act like a mirror to deflect aging UVA & burning UVB rays & can be less irritating than traditional chemical sunscreens.

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Photo-Brightening Moisturizer
Broad Spectrum SPF 30
Instant hydration & protection against environmental aggressors

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Photo-Brightening Moisturizer
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Vitamin C Ester, Alpha Lipoic Acid, Mineral-Based Sunscreen
€ 15 mL / 0.5 fl oz

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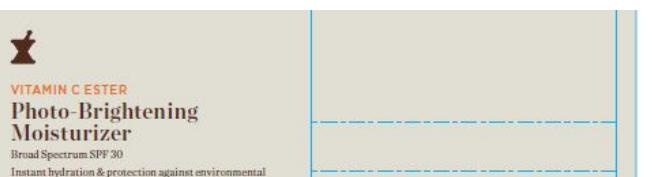
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DRUG FACTS (Continued)

Other Information: Protect the product in the container from excessive heat and direct sunlight.

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VITAMIN C ESTER
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Instant hydration & protection against environmental aggressors

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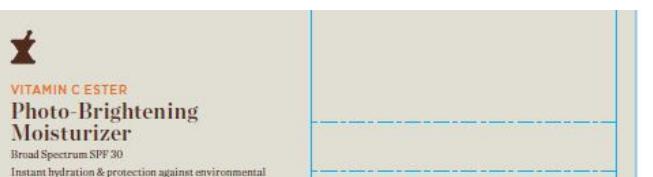
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Vitamin C Ester, Alpha Lipoic Acid, Mineral-Based Sunscreen
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Other Information: Protect the product in the container from excessive heat and direct sunlight.

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Drug Facts (Continued)

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.
- Not for use on children.
- **Caution:** Avoid prolonged sun exposure. 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 like seeking shade when possible, wearing long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients:

Water, Glycerin, Cetylpalmitate, Dimethicones, Petyl-
ene Glycol, Ethylhexyl Methoxycinnamate, Ethylhexyl Salicylate, Ethylhexyl Propionate, Ethylhexyl Acrylate, Acrylated Dimethyl Tauro Copolymer, Benzyl Alcohol, Aluminum Hydroxide, Butylene Glycol, Caprylic/Capric Triglyceride, Chitosan, Dimethicone, Ethylhexyl Stearate, Glycerin, Xanthan Gum, Hydrogenated Polyisobutylene, Thiodic Acid, Aloe Extract.

Other Information:

• Protect the product in this container from excessive heat and direct sun.

Questions? 1-800-820-7807

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Broad Spectrum SPF 30

59 mL / 2 fl oz

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KEY INGREDIENTS

Vitamin C Ester: Supercharged Brightening & Smoothing A more potent, highly stable & less absorbent form of antioxidant-rich vitamin C, Vitamin C Ester gives the appearance of collagen-rich skin by visibly smoothing, brightening & minimizing discoloration over time. Unlike traditional vitamin C, Vitamin C Ester is fat soluble & easily absorbable for maximum skin health & radiance.

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Mineral-Based Sunscreen: Advanced SPF Protection: Minerals found deep within the earth are ground into ultra-fine powders that act like a mirror to deflect aging UVA & burning UVB rays & can be less irritating than traditional chemical sunscreens.

Paraben-free

Ultra-lightweight, whipped texture immediately hydrates & protects against environmental aggressors while delivering brightening benefits over time. Formulated with mineral-based broad spectrum SPF for superior sun protection.

Drug Facts

Active Ingredient	Purpose
Titanium Dioxide (4.2%)	Sunscreen

Uses

- Helps prevent sunburn.
- When used in conjunction with other sun protection measures (see Directions), decreases the chance of skin cancer and early skin aging caused by exposure to the sun.

Warnings:

- Do not use on damaged or broken skin.
- Stop use and seek a doctor if irritation occurs.
- When using this product keep out of eyes. Rinse with water if eyes contact.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions:

- Apply to face in gentle circular motion in the morning. For best results, apply after your favorite Perricone MD serum, serum concentrate or facial cream.



UPC: 651473706014

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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 do not get it in your eyes. Rinse with water if you get it in your eyes. • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions • Apply to face & neck prior to sun exposure. For best results, apply after your favorite Perricone MD serum, serum concentrate or facial cream.

Drug Facts (Continued)

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. • Not for use on children under 6 months of age.
- **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 protective measures including:
 - Limit time in the sun, especially from 10 a.m.-2 p.m.
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Drug Facts (Continued)

Other Information Perricone MD product is the controller form of Quaternium-15. Quaternium-15 is a preservative that controls the growth of bacteria, fungi, and yeast. It is also used as a thickening agent in cosmetics and personal care products. It may cause allergic reactions in some people.



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Instant hydration & protection against environmental aggressors

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titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45634-254
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.48 g in 59 g

Inactive Ingredients

Ingredient Name	Strength
LEVOMENOL (UNII: 24WE03BX2T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

POLYSORBATE 60 (UNII: CAL22UVI4M)
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)
DIMETHICONE/VINYL DIMETHICONE CROSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
XANTHAN GUM (UNII: TTV12P4NEE)
DIMETHICONE CROSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
BENZYL ALCOHOL (UNII: LGK8494WBH)
STEARIC ACID (UNII: 4ELV7Z65AP)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ISOHEXADECANE (UNII: 918X1OUE1E)
THIOCTIC ACID (UNII: 73Y7P0K73Y)
PHOSPHOLIPASE D1 (UNII: RO5LD48GLV)
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
HAEMATOCOCCUS PLUVIALIS (UNII: 31T0FF0472)
TOCOPHEROL (UNII: R0ZB2556P8)
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPOENOYL CAPPED) (UNII: T9296U138P)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)
WATER (UNII: 059QF0KOOR)
GLYCERIN (UNII: PDC6A3C00X)
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45634-254-20	82 g in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	07/28/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	07/28/2022	

Establishment

Name	Address	ID/FEI	Business Operations
Dimensional Merchandising Inc (DMI)		076693183	manufacture(45634-254)

Revised: 7/2023

N.V Perricone LLC