

**INFINITEK PARIS BROAD SPECTRUM SPF 50 SUNSCREEN- titanium dioxide,
zinc oxide lotion
Prime Enterprises 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.

Infinitek Paris Tinted Mineral Face Sunscreen Lotion Broad Spectrum SPF 50

Active Ingredients

Titanium Dioxide 4%

Zinc Oxide 4%

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.

Purpose

Sunscreen

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 product is swallowed, get medical help or contact a poison control center right away.

Directions

- Apply liberally 15 minutes before sun exposure.
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- Reapply:
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 - After 80 minutes of swimming or sweating.
 - Immediately after towel drying.
 - At least every 2 hours.
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- **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:
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 - Limit time in the sun, especially from 10:00 a.m. to 2:00 p.m.
 - Wear long-sleeved shirt, pants, hats, and sunglasses.
 - Children under 6 months: Ask a doctor.

Other Information

Protect this product from excessive heat and direct sun.

Questions or Comments?

support@infinitekparis.com

INACTIVE INGREDIENTS

Allantoin, Alumina, Butyrospermum Parkii (Shea) Butter, Camellia Oleifera (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Cetyl PEG/PPG-10/1 Dimethicone, Cucumis Sativus (Cucumber) Extract, Cyclopentasiloxane, Dimethicone Crosspolymer, Distearidimonium Hectorite, Ethylhexylglycerin, Glycerin, Hexyl Laurate, Iron Oxides, Linum Usitatissimum (Linseed) Seed Oil, Oenothera Biennis (Evening Primrose) Oil, PEG-10 Dimethicone, Phenoxyethanol, Physalis Angulata Extract, Plankton Extract, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Rosa Canina Seed Oil, Silica, Stearic Acid, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

Infinitek Paris Tinted Mineral Sunscreen Broad Spectrum SPF 50 - 50 mL

Drug Facts

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Questions or comments?

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REG NSOC90338-19CO

Distributed and imported by/Distribuido e importado por:

Infinitek Paris LLC/United States

Natural VGP Nutrition S.A./Colombia

JAE MG S.A., DE C.V./Mexico

Made in the United States

From US and imported ingredients

www.infinitekparis.com

INFINITEK®
PARIS

ÉLÉMENTAIRE COLLECTION

ULTRA-PROTECTION

BROAD SPECTRUM
SPF 50

Sunscreen
Tinted Mineral Face Lotion

UVA/UVB Protection
Mate Finish
Water Resistant
(80 Minutes)

Protección UVA/UVB
Acabado Mate
Resistente al Agua
(80 Minutos)

Dermatologist Tested
Dermatológicamente Probado

1.75 FL.OZ / 50 mL

Modo de uso

Aplique 15 minutos antes de la exposición al sol.

Aplicar de nuevo:

- Después de 80 minutos de natación o sudoración.

- Inmediatamente después de secarse con una toalla.

- Al menos cada 2 horas.



Cruelty Free

Beneficios

Ayuda a prevenir las quemaduras solares. Si se usa como se indica con otras medidas de protección solar (ver Modo de uso), disminuye el riesgo del envejecimiento prematuro de la piel causado por el sol.

Precauciones

Sólo para uso externo. No lo use en la piel dañada o lastimada. Al usar este producto debe mantenerse fuera del área de los ojos. Enjuague con agua para eliminar. Si aparecen signos de irritación suspenda su uso. Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o un centro de control de inmediato.

INFINITEK PARIS BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0436
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	41.84 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	41.84 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ROSA CANINA SEED OIL (UNII: MHT97MG5P8)	
ALLANTOIN (UNII: 344S277G0Z)	
LINSEED OIL (UNII: 84XB4DV00W)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CUCUMBER SEED (UNII: BT3S9L53JK)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	

EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)
CAMELLIA OLEIFERA LEAF (UNII: 5077ELOC60)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
ALUMINUM OXIDE (UNII: LMI26O6933)
STEARIC ACID (UNII: 4ELV7Z65AP)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)
GLYCERIN (UNII: PDC6A3C0OX)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
WATER (UNII: 059QF0KO0R)
SHEA BUTTER (UNII: K49155WL9Y)
HEXYL LAURATE (UNII: 4CG9F9W01Q)

Product Characteristics

Color	brown (Light Tan)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0436-3	50 mL in 1 TUBE; Type 0: Not a Combination Product	05/20/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/20/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0436) , manufacture(58443-0436) , label(58443-0436) , analysis(58443-0436)

Revised: 10/2021

Prime Enterprises Inc.