

**PROTECTION U.V. BROAD SPECTRUM SPF 25- titanium dioxide, zinc oxide cream
B.R.**

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.

Protection U.V. Broad Spectrum SPF 25

Drug Facts

Active Ingredients

TITANIUM DIOXIDE 2.5 %

ZINC OXIDE 3.8%

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

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - 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 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 sleeve shirts, pants, hats, and sunglasses
- children under 6 months: ask a doctor

Inactive ingredients

Algae Extract, Alumina, Caprylic/Capric Triglyceride, Caprylyl Glycol, Carnosine, Diatomaceous Earth, Dicaprylyl Carbonate, Ethyl Ferulate, Ethylhexylglycerin, Glycerin, Isostearic Acid, Laminaria Ochroleuca Extract, Lecithin, Magnesium Sulfate, Mannitol, Octyldodecanol, Octyldodecyl Xyloside, Oryzanol, PEG-30 Dipolyhydroxystearate, PEG-8 Laurate, Pentylene Glycol, Phaeodactylum Tricornutum Extract, Phenoxyethanol, Polyamide-5, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Pongamia Glabra Seed Oil, Silybum Marianum Fruit Extract, Stearic Acid, Styrene/Acrylates Copolymer, Tocopherol, Water (Aqua), Xanthan Gum, Zinc Sulfate.

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

USA

BIOLOGIQUE RECHERCHE

261 Fifth Avenue, Suite 2000

NY 10016 New York USA

1-212-989-6077

usa@biologique-recherche.com

www.biologique-recherche.us

CANADA

THE PRINCIPLES BRANDS

349 St.Clair Ave West, Suite 104

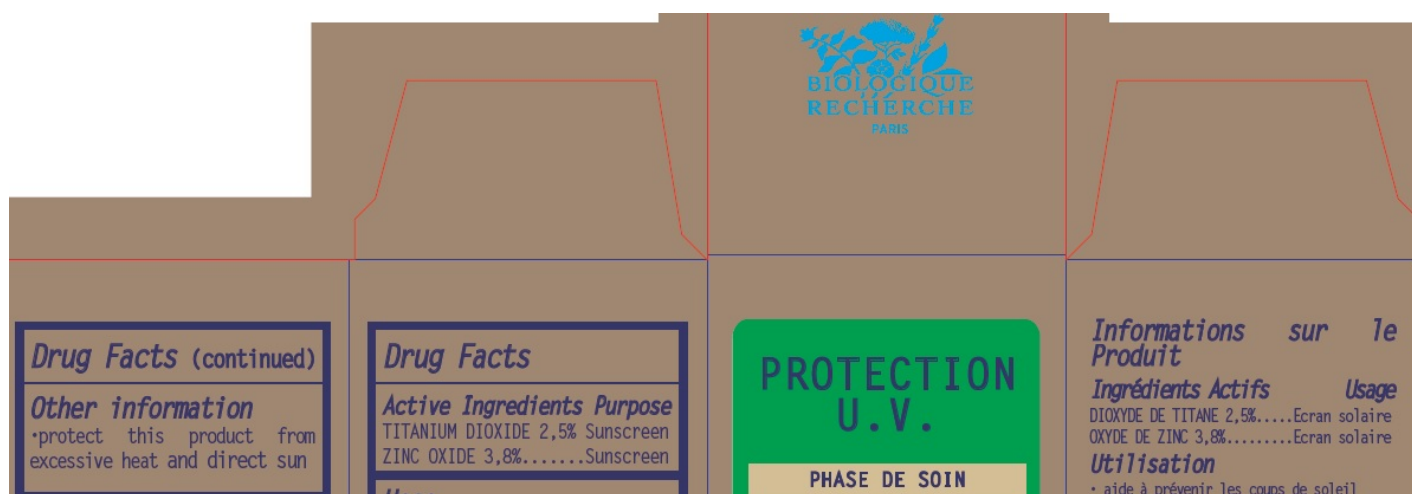
TORONTO, ON M5P 1N3

416-464-8852

info@theprinciplesbrands.com

www.theprinciplebrands.com

Package Labeling:



Questions or comments?

USA

BIOLOGIQUE RECHERCHE
261 Fifth Avenue, Suite 2000
NY 10016 New York USA
1-212-989-6077
usa@biologique-recherche.com
www.biologique-recherche.us

CANADA

THE PRINCIPLES BRANDS
349 St.Clair Ave West, Suite 104
TORONTO, ON M5P 1N3
416-464-8852
info@theprinciplesbrands.com
www.theprinciplebrands.com

ETUIPROSOLUS / A



BIOLOGIQUE RECHERCHE
32, avenue des Champs-Élysées - 75008 PARIS
MADE IN FRANCE
www.biologique-recherche.com

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

Directions

• apply liberally 15 minutes before sun exposure

• reapply:

• after 40 minutes of swimming or sweating

• immediately after towel drying

• 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 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 sleeve shirts, pants, hats, and sunglasses

• children under 6 months: ask a doctor

Inactive ingredients

Algae Extract, Alumina, Caprylic/Capric Triglyceride, Caprylyl Glycol, Camosine, Diatomaceous Earth, Dicaprylyl Carbonate, Ethyl Ferulate, Ethylhexylglycerin, Ferulic Acid, Glycerin, Glycine Soja (Soybean) Oil, Isostearic Acid, Laminaria Ochroleuca Extract, Lecithin, Magnesium Sulfate, Mannitol, Octyldodecanol, Octyldodecyl Xylolide, Oryzanol, Peg-30 Dipolyhydroxystearate, Peg-8 Laurate, Pentylene Glycol, Phaeodactylum Tricomutum Extract, Phenoxyethanol, Polyamide-5, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Pongamia Glabra Seed Oil, Silybum Marianum Fruit Extract, Stearic Acid, Styrene/Acrylates Copolymer, Tocopherol, Water (Aqua), Xanthan Gum, Zinc Sulfate.

Protection solaire
pour le visage avec
Triple Shield Complex®

Sunscreen cream
for face with
Triple Shield Complex®

**BROAD SPECTRUM
SPF 25**



50 ml

1.7 FL.OZ

• si utilisé comme indiqué avec d'autres mesures de protection solaire (voir Instructions), diminue le risque de cancer de la peau et le vieillissement cutané prématuré causé par le soleil.

Précautions d'emploi

Usage externe uniquement. Ne pas appliquer sur des peaux excoriées ou irritées. Éviter le contact avec les yeux. En cas de contact, rincer à l'eau claire. Arrêter l'utilisation du produit et consulter un médecin si des rougeurs apparaissent. Garder hors de portée des enfants. En cas d'ingestion, consulter un médecin ou un Centre Antipoison immédiatement.

Instructions

• appliquer généreusement 15 minutes avant l'exposition au soleil.

• réappliquer :

• immédiatement après le séchage avec une serviette

• au moins toutes les 2 heures

• Mesures de protection solaire. La surexposition au soleil augmente le risque de cancer de la peau et le vieillissement prématuré de la peau. Pour diminuer ce risque, appliquer régulièrement une protection solaire broad spectrum SPF 15 ou plus et respecter d'autres mesures de protection solaire comme :

• limiter l'exposition solaire, en particulier entre 10h et 14h.

• porter des chemises à manches longues, pantalons, chapeaux et lunettes de soleil.

• enfants de moins de 6 mois : demander l'avis d'un médecin.

Ingredients non actifs

Algae Extract, Alumina, Caprylic/Capric Triglyceride, Caprylyl Glycol, Camosine, Diatomaceous Earth, Dicaprylyl Carbonate, Ethyl Ferulate, Ethylhexylglycerin, Ferulic Acid, Glycerin, Glycine Soja (Soybean) Oil, Isostearic Acid, Laminaria Ochroleuca Extract, Lecithin, Magnesium Sulfate, Mannitol, Octyldodecanol, Octyldodecyl Xylolide, Oryzanol, Peg-30 Dipolyhydroxystearate, Peg-8 Laurate, Pentylene Glycol, Phaeodactylum Tricomutum Extract, Phenoxyethanol, Polyamide-5, Polyglyceryl-3 Polyricinoleate, Polyhydroxystearic Acid, Pongamia Glabra Seed Oil, Silybum Marianum Fruit Extract, Stearic Acid, Styrene/Acrylates Copolymer, Tocopherol, Water (Aqua), Xanthan Gum, Zinc Sulfate.

Autres informations

• protéger le produit de la chaleur et du soleil direct.

Questions ou commentaires?

CANADA

THE PRINCIPLES BRANDS
349 St.Clair Ave West, Suite 104
TORONTO, ON M5P 1N3
416-464-8852
info@theprinciplesbrands.com
www.theprinciplebrands.com



3 700693 204408 >

PROTECTION U.V.

PHASE DE SOIN

Protection solaire pour le visage
avec Triple Shield Complex®

Sunscreen cream for face
with Triple Shield Complex®

**BROAD SPECTRUM
SPF 25**



50ml

1.7 FL.OZ

MODE D'UTILISATION : Appliquer généreusement sur l'ensemble du visage, du cou et du décolleté 15 minutes avant l'exposition au soleil. Si vous n'appliquez pas suffisamment de produit, le niveau de protection solaire sera considérablement réduit. Réappliquer au moins toutes les deux heures. Appliquer immédiatement après le séchage avec une serviette. Pour l'utilisation sur des enfants de moins de 6 mois, demander l'avis d'un médecin. Mesures de protection solaire : La surexposition au soleil augmente le risque de cancer de la peau et le vieillissement prématuré de la peau. Pour diminuer ce risque, appliquer régulièrement une protection solaire broad spectrum SPF 15 ou plus et respecter d'autres mesures de protection solaire comme : limiter l'exposition solaire, en particulier entre 10h et 14h et porter maillots à manches longues, pantalons, chapeaux et lunettes de soleil.

INGREDIENTS ACTIFS : Dioxyde de Titane, Oxyde de Zinc.

PRÉCAUTIONS D'EMPLOI : Usage externe uniquement. Ne pas appliquer sur des peaux excoriées ou irritées. Éviter le contact avec les yeux. En cas de contact, rincer à l'eau claire. Arrêter l'utilisation du produit et consulter un médecin si des rougeurs apparaissent. Garder hors de portée des enfants. En cas d'ingestion, consulter un médecin ou un Centre Antipoison immédiatement.

DIRECTIONS FOR USE: Apply generously to the entire face, neck and décolleté 15 minutes before sun exposure. If you do not apply enough product, the level of the sun protection will be considerably reduced. Reapply at least every two hours. Apply immediately after towel drying. For use on children less than 6 months of age, consult a health care practitioner. Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF of 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m. to 2 p.m.; and wear long-sleeved shirts, pants, hats, and sunglasses.

ACTIVE INGREDIENTS: Titanium Dioxide, Zinc Oxide.

CAUTIONS: 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.

BIOLOGIQUE RECHERCHE

32, avenue des Champs-Élysées - 75008 PARIS

MADE IN FRANCE

www.biologique-recherche.com



PROTECTION U.V. BROAD SPECTRUM SPF 25

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69332-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	25 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	38 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LM26O6933)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CARNOSINE (UNII: 8HO6PVN24W)
DIATOMACEOUS EARTH (UNII: 2RF6EJ0M85)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
ETHYL FERULATE (UNII: 5B8915UELW)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
ISOSTEARIC ACID (UNII: X33R8U0062)
LAMINARIA OCHROLEUCA (UNII: 4R2124HE76)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
MANNITOL (UNII: 3OWL53L36A)
OCTYLDODECANOL (UNII: 461N10614Y)
GAMMA ORYZANOL (UNII: SST9XCL51M)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
PEG-8 LAURATE (UNII: 762O8IWA10)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
PHAEODACTYLUM TRICORNUTUM (UNII: Y5W63E7HLV)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
KARUM SEED OIL (UNII: 62160PU6FJ)
MILK THISTLE (UNII: U946SH95EE)
STEARIC ACID (UNII: 4ELV7Z65AP)
TOCOPHEROL (UNII: R0ZB2556P8)
WATER (UNII: 059QF0KO0R)
XANTHAN GUM (UNII: TTV12P4NEE)
ZINC SULFATE (UNII: 89DS0H96TB)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69332-001-50	1 in 1 CARTON	11/02/2014	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69332-001-00	1 in 1 CARTON	11/02/2014	
2		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69332-001-04	4 mL in 1 TUBE; Type 0: Not a Combination Product	06/06/2017	10/31/2019

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/02/2014	

Labeler - B.R. (296150530)

Establishment

Name	Address	ID/FEI	Business Operations
B.R.		296150530	manufacture(69332-001)