

**HAUTE PROTECTION HIGH PROTECTION TINTED COMPACT BROAD SPECTRUM
SPF 50 BEIGE- titanium dioxide, zinc oxide cream**

Pierre Fabre USA 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.

HAUTE PROTECTION High Protection Tinted Compact Broad Spectrum SPF 50

Active ingredients

TITANIUM DIOXIDE 13.7 %

ZINC OXIDE 4.9 %

Purpose

Sunscreen

Uses

- Tinted compact SPF 50 helps prevent sunburn.
- If used as directed with other sun protection measures (see **Directions for use**), decreases the risk if 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 consult a health care practitioner 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 for use

- Apply liberally/generously and evenly 15 minutes before sun exposure.
- Reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours.
- Children under 6 months: Consult a health care practitioner.
- **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 skin protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats and sunglasses.

Inactive Ingredients

DIMETHICONE, HYDROGENATED POLYISOBUTENE, PHENYL TRIMETHICONE, ISODECYL NEOPENTANOATE, SQUALANE, TALC, ETHYLHEXYL HYDROXYSTEARATE, POLYETHYLENE, POLYMETHYL METHACRYLATE, SILICA, WATER/EAU, POLYGLYCERYL-3 DIISOSTEARATE, ALUMINA, STEARIC ACID, BEESWAX, BHT, CAPRYLIC/CAPRIC TRIGLYCERIDE, MICROCRYSTALLINE WAX, PHENOXYETHANOL, TOCOPHEROL, TOCOPHERYL GLUCOSIDE, TRIBEHENIN, TRIETHOXYCAPRYLYLSILANE, TITANIUM DIOXIDE (CI77891), IRON OXIDES (CI77492), (CI77491), (CI77499)

Other Information

Protect this product from excessive heat and direct sun.

HAUTE PROTECTION High Protection Tinted Compact Broad Spectrum SPF 50 BEIGE 10g (67015-2036-0)

HAUTE

PROTECTION

HIGH PROTECTION

Fragrance-free

SPF 50 UVB UVA Broad spectrum

Water-resistant

40 minutes

Beige

Tinted compact

For intolerant skin

PARIS

10g e/NET WT. 0.3 OZ.- NPN80085668

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|--|---|--|---|
| <p>Drug Facts / Informations Pharmaceutiques</p> <p>Active ingredients / Ingrédients actifs TITANIUM DIOXIDE / DIOXYDE DE TITANE 13.7 % ZINC OXIDE / OXYDE DE ZINC 4.9 %</p> <p>Purpose / Objectif Sunscreen / Ecran solaire Sunscreen / Ecran solaire</p> <p>Uses / Indications • Tinted compact SPF 50 helps prevent sunburn. • If used as directed with other sun protection measures (see Directions for use), decreases the risk of skin cancer and early skin aging caused by the sun. • La compact teinté FPS 50 aide à prévenir les coups de soleil. • Si le produit est utilisé selon les instructions avec d'autres mesures de protection contre le soleil (voir Mode d'emploi), le risque de cancer de la peau et de vieillissement prématuré de la peau causé par le soleil est réduit.</p> <p>Warnings / Précautions For external use only. / Pour usage externe seulement. Do not use on damaged or broken skin. / Ne pas utiliser sur la peau endommagée ou présentant des lésions.</p> <p>When using this product, keep out of eyes. Rinse with water to remove. / Eviter tout contact avec les yeux. Rincer à l'eau le cas échéant.</p> <p>Stop use and consult a health care practitioner if rash occurs. / Cesser l'utilisation et consulter un professionnel de la santé si des éruptions apparaissent.</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. / Garder hors de portée des enfants. En cas d'ingestion, faire appel à une aide médicale immédiatement ou contacter un centre antipoison.</p> <p>Directions for use • Apply liberally/generously and evenly 15 minutes before sun exposure. • Reapply: • after 40 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours. • Children under 6 months: Consult a health care practitioner. • 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. to 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses.</p> <p>Mode d'emploi • Appliquer abondamment/généreusement et uniformément 15 minutes avant l'exposition au soleil. • Réappliquer: • après 40 minutes de baignade ou transpiration • immédiatement après séchage à la serviette • au moins toutes les 2 heures. • Pour les enfants de moins de 6 mois: consulter un professionnel de la santé. • Mesure de protection contre le soleil: passer du temps au soleil augmente le risque de cancer de la peau et de vieillissement prématuré de la peau. Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran solaire avec un FPS à large spectre d'au moins 15 et d'appliquer d'autres mesures de protection contre le soleil, telles que: • limiter le temps passé au soleil, notamment entre 10 et 14 heures • porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil.</p> | <p>Drug Facts (continued) / Informations Pharmaceutiques</p> <p>Non-medical (inactive) ingredients / Ingrédients non-médicaux (inactifs) DIMETHICONE, HYDROGENATED POLYISOBUTENE, PHENYL TRIMETHICONE, ISODECYL NEOPENTANOATE, SQUALANE, TALC, ETHYLHEXYL HYDROXYSTEARATE, POLYETHYLENE, POLYMETHYL METHACRYLATE, SILICA, WATER, POLYGLYCERYL-3 DIISOSTEARATE, ALUMINA, STEARIC ACID, BEESWAX, BHT, CAPRYLIC/CAPRIC TRIGLYCERIDE, MICROCRYSTALLINE WAX, PHENOXYETHANOL, TOCOPHEROL, TOCOPHERYL GLUCOSIDE, TRIBEHENIN, TRIETHOXYCAPRYLYLSILANE, TITANIUM DIOXIDE (CI77891), IRON OXIDES (CI77492), (CI77491), (CI77499)</p> <p>Other information / Autre information • Protect this product from excessive heat and direct sun. / • Ne pas exposer ce produit à des températures excessives ou au soleil.</p> | <p>HAUTE PROTECTION HIGH PROTECTION</p> <p>Sans parfum - Fragrance-free Résistant à l'eau - Water-resistant 40 minutes</p> <p>Sable - Beige</p> <p>FPS SPF 50 UVB (UVA)</p> <p>Large spectre Broad spectrum</p> <p>Compact teinté - Tinted compact Peaux intolérantes - For intolerant skin</p> <p>PARIS</p> <p>10g e/NET WT. 0.3 OZ.- NPN 80085668</p> | <p>Questions? 1-866-41-AVENE (28363) (USA) 1-877-441-2011 (CAN)</p> <p><small>Touté par des dermatologues sur des peaux sensibles. Tested on sensitive skin by dermatologists.</small></p> <p>Élaboré en vue de minimiser les risques de réactions allergiques - Non comédogène. Formulated to minimize risks of allergic reactions - Non-comedogenic.</p> <p>Pierre Fabre Dermo-Cosmétique</p> <p>Laboratoires Dermatologiques Avène 43, allée Albert-Coste 92100 Boulogne Paris - France Import / Dist. by: Pierre Fabre Dermo-Cosmétique Canada 9955 rue de Châteaufort, suite 115 Brossard (Qué.) J4Z 3V8-Canada Pierre Fabre Dermo-Cosmétique USA 8, Campus Drive Parsippany, NJ 07054 - U.S.A. Fabriqué en Italie - Made in Italy www.eculhermelaavene.com</p> |
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HAUTE PROTECTION HIGH PROTECTION TINTED COMPACT BROAD SPECTRUM SPF 50 BEIGE

titanium dioxide, zinc oxide cream

Product Information

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|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67015-2036 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 4.9 g in 100 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 13.7 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| FERRIC OXYHYDROXIDE (UNII: 87PZU03K0K) | |
| HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E) | |
| TRIBEHENIN (UNII: 8OC9U7TQZ0) | |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11) | |
| SQUALANE (UNII: GW89575KF9) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) | |
| TALC (UNII: 7SEV7J4R1U) | |
| ISODECYL NEOPENTANOATE (UNII: W60VYE24XC) | |
| PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8) | |
| ETHYLHEXYL HYDROXYSTEARATE (UNII: B7I80BVV5E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:67015-2036-1 | 1 in 1 CARTON | 03/15/2019 | |
| 1 | NDC:67015-2036-0 | 10 g in 1 CONTAINER; 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 | 03/15/2019 | |

Labeler - Pierre Fabre USA Inc. (117196928)

Registrant - Pierre Fabre USA Inc. (117196928)

Revised: 6/2019

Pierre Fabre USA Inc.