

**HAUTE PROTECTION HIGH PROTECTION TINTED COMPACT BROAD SPECTRUM
SPF 50 BEIGE- titanium dioxide, zinc oxide cream
Pierre Fabre USA Inc.**

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 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 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, POLYGLYCERLYL-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

<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. / • Le 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. When using this product, keep out of eyes. Rinse with water to remove. / Éviter tout contact avec les yeux. Rincer à l'eau le cas échéant. 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 • Appliquez abondamment/généreusement et uniformément 15 minutes avant l'exposition au soleil. • Réappliquez: • 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, consultez 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>Nonmedicinal (inactive) ingredients / Ingrédients non-médicamenteux (inactifs) TRIFLUORÉTHYL PARABÈNE, POLYBUTÈNE-1, POLYBUTÈNE-3, POLYBUTÈNE-10, POLYBUTÈNE-12, POLYBUTÈNE-14, POLYBUTÈNE-16, POLYBUTÈNE-18, POLYBUTÈNE-20, POLYBUTÈNE-22, POLYBUTÈNE-24, POLYBUTÈNE-26, POLYBUTÈNE-28, POLYBUTÈNE-30, POLYBUTÈNE-32, POLYBUTÈNE-34, POLYBUTÈNE-36, POLYBUTÈNE-38, POLYBUTÈNE-40, POLYBUTÈNE-42, POLYBUTÈNE-44, POLYBUTÈNE-46, POLYBUTÈNE-48, POLYBUTÈNE-50, POLYBUTÈNE-52, POLYBUTÈNE-54, POLYBUTÈNE-56, POLYBUTÈNE-58, POLYBUTÈNE-60, POLYBUTÈNE-62, POLYBUTÈNE-64, POLYBUTÈNE-66, POLYBUTÈNE-68, POLYBUTÈNE-70, POLYBUTÈNE-72, POLYBUTÈNE-74, POLYBUTÈNE-76, POLYBUTÈNE-78, POLYBUTÈNE-80, POLYBUTÈNE-82, POLYBUTÈNE-84, POLYBUTÈNE-86, POLYBUTÈNE-88, POLYBUTÈNE-90, POLYBUTÈNE-92, POLYBUTÈNE-94, POLYBUTÈNE-96, POLYBUTÈNE-98, POLYBUTÈNE-100.</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 style="text-align: center;">HAUTE PROTECTION HIGH PROTECTION</p> <p style="text-align: center;">Sans parfum - Fragrance-free Résistant à l'eau - Water-resistant 40 minutes</p> <p style="text-align: center;">Sable - Beige</p> <p style="text-align: center;">Compact teinté - Tinted compact Peaux intolérantes - For intolerant skin</p> <p style="text-align: center;">FPS SPF 50 UVB UVA Large spectre Broad spectrum</p> <p style="text-align: center;">PARIS 10 g e / NET WT. 0.3 OZ. - NPN 80085668</p>	<p>Questions? 1-866-41-AVENE (28363) (USA) 1-877-441-2011 (CAN)</p> <p>Tout ce qui dermatiques et de peau sensibles. Testé et trouvé sûr par dermatologues.</p> <p>Elaboré en vue de minimiser les risques de réactions allergiques - Non comédogène. Formulé pour minimiser les risques de réactions allergiques - Non comédogène.</p>   <p>Pierre Fabre Dermo-Cosmétique Laboratoires Dermatologiques Avène 45 place Albatros 92100 Nanterre - Paris - France Les Cosmétiques 1300 L'Avène - France Import / Dist. by: Pierre Fabre Dermo-Cosmétique Canada 9955 rue de Châteaufort, suite 115 Brossard (QC) J4Z 1V3-Canada Pierre Fabre Dermo-Cosmétique USA 8 Campus Drive Parippany, NJ 07054 - U.S.A. Fabriqué en Italie - Made in Italy www.eau-thermale-avene.com</p>
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HAUTE PROTECTION HIGH PROTECTION TINTED COMPACT BROAD SPECTRUM SPF 50 BEIGE

titanium dioxide, zinc oxide cream

Product Information

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: EX43802MRT)	
FERROFERRIC 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)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TRIBEHENIN (UNII: 80C9U7TQZ0)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ALUMINUM OXIDE (UNII: LMI2606933)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
SQUALANE (UNII: GW89575KF9)	
TOCOPHEROL (UNII: ROZB2556P8)	
PHENOXYETHANOL (UNII: HIE492Z3ZT)	

YELLOW WAX (UNII: 2ZA36H0S2V)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TALC (UNII: 7SEV7J4R1U)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
PHENYL TRIMETHICONE (UNII: DROK5NOJ4R)	
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 Drug	M020	03/15/2019	

Labeler - Pierre Fabre USA Inc. (117196928)

Registrant - Pierre Fabre USA Inc. (117196928)