

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

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**HAUTE PROTECTION High Protection Tinted Compact Broad Spectrum SPF 50  
Honey**

**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 (CI77491), (CI77492), (CI77499)

### **Other Information**

Protect this product from excessive heat and direct sun.

### **HAUTE PROTECTION High Protection Tinted Compact Broad Spectrum SPF 50 HONEY 10g (67015-2035-0)**

HAUTE

PROTECTION

*HIGH PROTECTION*

Fragrance-free

SPF 50 UVB UVA Broad spectrum

Water-resistant

40 minutes

Honey

Tinted compact

For intolerant skin

PARIS

10g e/NET WT. 0.3 OZ.- NPN 80085664

<p><b>Drug Facts / Informations Pharmaceutiques</b></p> <p><b>Active ingredients / Ingrédients actifs</b>  TITANIUM DIOXIDE / DIOXYDE DE TITANE 13.7 %  ZINC OXIDE / OXYDE DE ZINC 4.9 %</p> <p><b>Purpose / Objectif</b>  Sunscreen / Ecran solaire  Sunscreen / Ecran solaire</p> <p><b>Uses / Indications</b> • 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><b>Warnings / Précautions</b> 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.</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 ou immédiatement au contact d'un centre antipoison.</p> <p><b>Directions for use</b> • 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: • limiting time in the sun, especially from 10 a.m. to 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses.</p> <p><b>Mode d'emploi</b> • 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 h et 14 heures • porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil.</p>	<p><b>Drug Facts (continued) / Informations Pharmaceutiques</b></p> <p><b>Nonmedicinal (inactive) ingredients / Ingrédients non-médicamenteux (inactifs)</b> BUTYLENE GLYCOL, POLYBUTENE-1, POLYBUTENE-3, POLYBUTENE-4, POLYBUTENE-6, POLYBUTENE-10, POLYBUTENE-12, POLYBUTENE-14, POLYBUTENE-16, POLYBUTENE-18, POLYBUTENE-20, POLYBUTENE-22, POLYBUTENE-24, POLYBUTENE-26, POLYBUTENE-28, POLYBUTENE-30, POLYBUTENE-32, POLYBUTENE-34, POLYBUTENE-36, POLYBUTENE-38, POLYBUTENE-40, POLYBUTENE-42, POLYBUTENE-44, POLYBUTENE-46, POLYBUTENE-48, POLYBUTENE-50, POLYBUTENE-52, POLYBUTENE-54, POLYBUTENE-56, POLYBUTENE-58, POLYBUTENE-60, POLYBUTENE-62, POLYBUTENE-64, POLYBUTENE-66, POLYBUTENE-68, POLYBUTENE-70, POLYBUTENE-72, POLYBUTENE-74, POLYBUTENE-76, POLYBUTENE-78, POLYBUTENE-80, POLYBUTENE-82, POLYBUTENE-84, POLYBUTENE-86, POLYBUTENE-88, POLYBUTENE-90, POLYBUTENE-92, POLYBUTENE-94, POLYBUTENE-96, POLYBUTENE-98, POLYBUTENE-100.</p> <p><b>Other information / Autre information</b> • Protect this product from excessive heat and direct sun. / Ne pas exposer ce produit à des températures excessives ou au soleil.</p>	<p><b>HAUTE PROTECTION</b>  <b>HIGH PROTECTION</b></p> <p>Sans parfum - Fragrance-free  Résistant à l'eau - Water-resistant  40 minutes</p> <p>Doré - Honey</p> <p>SPF 50  Large spectre  Broad spectrum</p> <p>Compact teinté - Tinted compact  Peaux intolérantes - For intolerant skin</p> <p>PARIS  10 g e / NET WT. 0.3 OZ. - NPN 80085664</p>	<p><b>Questions?</b>  1-866-41-AVENE  (28363) (USA)  1-877-441-2011 (CAN)</p> <p>Elaboré en vue de minimiser les risques de réactions allergiques -  Formulated to minimize risks of allergic reactions -  Non-comédogène -  Non-comedogenic.</p> <p><b>Pierre Fabre Derma-Cosmétique</b>  Laboratoires  Dermatologiques Avène  45, place Abel-Gance  92100 Boulogne - Paris - France  Le Cannol (Canada) - 8550 (Canada) - France  Import / Dist. by:  Pierre Fabre Derma-Cosmétique  Canada  9955 rue de Châteaufort, suite 115  Brossard (QC), J4Z 3V5-Canada  Pierre Fabre Derma-Cosmétique USA  8 Campus Drive  Parsippany, NJ 07054-1154  Fabriqué en Italie - Made in Italy  www.avenemalavene.com</p>
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# HAUTE PROTECTION HIGH PROTECTION TINTED COMPACT BROAD SPECTRUM SPF 50 HONEY

titanium dioxide, zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67015-2035
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX43802MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>FERRIC OXYHYDROXIDE</b> (UNII: 87PZU03K0K)	
<b>HYDROGENATED POLYBUTENE (1300 MW)</b> (UNII: 7D1YQ9Y5EZ)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>TRIBEHENIN</b> (UNII: 80C9U7TQZ0)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>PHENOXYETHANOL</b> (UNII: HIE492Z33T)	

<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>ISODECYL NEOPENTANOATE</b> (UNII: W60VYE24XC)	
<b>PHENYL TRIMETHICONE</b> (UNII: DROK5NOJ4R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)	
<b>ETHYLHEXYL HYDROXYSTEARATE</b> (UNII: B7I80BVV5E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67015-2035-1	1 in 1 CARTON	06/03/2019	
1	NDC:67015-2035-0	10 g in 1 CONTAINER; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/03/2019	

**Labeler** - Pierre Fabre USA Inc. (117196928)

**Registrant** - Pierre Fabre USA Inc. (117196928)