

**EAU THERMALE AVENE TINTED MINERAL SUNSCREEN FLUID SPF 50 PLUS- titanium dioxide, zinc oxide lotion**

**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.*

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**Eau Thermale Avene Tinted Mineral Sunscreen Fluid SPF 50 Plus**

***Drug Facts***

***Active ingredients***

Titanium Dioxide 11.42%

Zinc Oxide 14.6%

***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 eyes 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***

- Shake well before use
- Apply liberally 15 minutes before sun exposure
- Reapply:
  - after 80 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

### ***Other information***

- Protect this product from excessive heat and direct sun.

### ***Inactive ingredients***

WATER, COCO-CAPRYLATE/CAPRATE, ISOPROPYL PALMITATE, ISOCETYL STEAROYL STEARATE, ISODECYL NEOPENTANOATE, ISODODECANE, ISOHEXADECANE, PTFE, TRIETHYLHEXANOIN, DICAPRYLYL ETHER, PEG-30 DIPOLYHYDROXYSTEARATE, IRON OXIDES, MICA, ALUMINA, STEARIC ACID, CAPRYLYL GLYCOL, PEG-45/DODECYL GLYCOL COPOLYMER, SILICA, BENZOIC ACID, CAPRYLIC/CAPRIC TRIGLYCERIDE, DISODIUM EDTA, DISTEARDIMONIUM HECTORITE, GLYCERYL BEHENATE, GLYCERYL DIBEHENATE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, PENTAERYTHRITYL TETRA-DI-T-BUTYL, HYDROXYHYDROCINNAMATE, POLYAMIDE-3, SODIUM CHLORIDE, TITANIUM DIOXIDE, TOCOPHEROL, TOCOPHERYL GLUCOSIDE, TRIBEHENIN, TRIETHOXYCAPRYLYLSILANE.

### ***Questions or comments?***

visit [www.aveneusa.com](http://www.aveneusa.com) or call toll-free 1-866-41-AVENE (28363)

### **Principal Display Panel - 40 mL Carton**

EAU THERMALE

Avene

VERY HIGH PROTECTION

Broad spectrum SPF 50+

Water resistant (80 minutes)

Chemical filter-free

Antioxidant

SPF 50+ UVB/UVA

Tinted Mineral

Sunscreen Fluid

FRAGRANCE-FREE

For sensitive skin, intolerant skin

PARIS

1.35 FL. OZ. (40 mL)

<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> <span style="float: right;"><b>Purpose</b></span>  <b>TITANIUM DIOXIDE</b> 11.4 % ..... Sunscreen  <b>ZINC OXIDE</b> 14.6 % ..... Sunscreen</p> <p><b>Uses</b> • Helps prevent sunburn • If used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun.</p> <p><b>Warnings</b>  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.</p> <p><b>Stop use and ask a doctor if rash occurs.</b></p> <p><b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> • Shake well before use • Apply liberally 15 minutes before sun exposure • Reapply: • after 80 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. to 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses. • Children under 6 months: Ask a doctor.</p> <p><b>Other information</b> • Protect this product from excessive heat and direct sun.</p> <p><b>Inactive ingredients</b>  WATER, COCO-CAPRYLATE/CAPRATE, BORNOPYL PALMITATE, ISOCETYL STEAROYL STEARATE, ISODECYL NEOPENTANOATE, ISODODECANE, ISOHEXADECANE, PTFE, TRIETHYLHEXANOIN, LECAPRYLYL ETHER, PEG-30 DIMETHYLDIMETHYLSEBACATE, ALLUMINA, STEARIC ACID, CAPRYLYL GLYCOL, PEG-45/DIODECYL GLYCOL COPOLYMER, SILICA, BENZOIC ACID, CAPRYLIC/CAPRIC TRIGLYCERIDE, DIMETHOXYETHYL DIBEAROXYMONIUM HEXAFLUOROPHOSPHATE, GLYCERYL BEHENATE, GLYCERYL DIBEHENATE, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, PENTAERYTHRITYL TETRA-2,4-BUTYL HYDROXYHYDROXYNANATE POLYMER-3, SODIUM CHLORIDE, TOCOPHEROL, TOCOPHERYL GLUCOSIDE, TRIETHYLHEXANOIN, TRIETHOXYCAPRYLYLSILANE, IRON OXIDES, MICA, TITANIUM DIOXIDE.</p> <p><b>Questions or comments?</b>  visit <a href="http://www.avenesa.com">www.avenesa.com</a> or call toll-free 1-866-41-AVENE (28363)</p>	<p><b>Tinted Mineral Sunscreen Fluid</b>  <b>Broad spectrum SPF 50+</b>  <b>Face</b></p> <p>A chemical filter-free sunscreen with 100% mineral UVA/UVB filters and powerful antioxidant protection, offering hydration in a lightweight lotion. Absorbs quickly into the skin with a matte finish. The universal shade provides sheer coverage for a natural look and even complexion. For skin intolerant to chemical filters and fragrance. Tested on sensitive skin.</p> <p><b>PROPERTIES</b></p> <ul style="list-style-type: none"> <li>• 100% mineral UVA/UVB broad spectrum protection</li> <li>• Photocopherol, a photosable form of Vitamin E, provides powerful antioxidant protection and helps absorb free radicals generated by sun exposure and environmental aggressors</li> <li>• Water resistant (80 minutes)</li> <li>• Provides hydration, ideal for daily use</li> <li>• Matte finish</li> </ul> <p><b>Fluide minéral teinté</b>  <b>Large spectre SPF 50+</b>  <b>Visage</b></p> <p>Ce soin solaire, sans filtre chimique, est composé de filtres 100 % minéraux UVB/UVA et d'un puissant pouvoir antioxydant.</p> <p>Voile peau est protégée, hydratée par cette texture légère. La pénétration du soin est rapide, le fini est mat.</p> <p>Grâce à sa teinte universelle, ce soin offre une couvrance naturelle et votre teint est unifié.</p> <p>Testé sur les peaux sensibles et intolérantes aux filtres chimiques et aux parfums.</p>	<p>EAU THERMALE  <b>Avène</b></p> <p>VERY HIGH PROTECTION</p> <p>Broad spectrum SPF 50+  Water resistant (80 minutes)  Chemical filter-free  Antioxidant</p> <p>SPF 50+  UVB (UVA)</p> <p><b>Tinted Mineral Sunscreen Fluid</b>  FRAGRANCE-FREE</p> <p>For sensitive, intolerant skin</p> <p>PARIS  1.3 FL. OZ. / 40 ml</p>	<p><b>OUR SENSITIVE SKIN EXPERTISE</b></p> <ul style="list-style-type: none"> <li>• Understanding the skin physiology, Avène Hydrotherapy Center has been providing treatments dedicated to dermatology since 1763.</li> <li>• The science of formulation: unique combination of Avène Thermal Spring Water with its soothing, calming and soothing properties and a strict selection of innovative ingredients.</li> <li>• Skin care products developed by taking inspiration from pharmaceutical standards: tests of efficiency and tolerance under dermatological control, textures developed for the best security of sensitive skin.</li> </ul> <p>✓ Chemical filter-free  ✓ Fragrance-free  ✓ Dermatologist tested</p> <p>Formulated to minimize risk of allergic reactions • Non-comedogenic.</p> <p><b>Pierre Fabre</b>  <b>Derma-Cosmétique</b></p> <p><b>Laboratoire Dermatologique Avène</b>  45, Avenue Albert Clouet  92100, Boulogne-Billancourt - France</p> <p>Distributed by:  Pierre Fabre USA, Inc  Parsippany, NJ 07054  Made in France</p>
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## EAU THERMALE AVENE TINTED MINERAL SUNSCREEN FLUID SPF 50 PLUS

titanium dioxide, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:670 15-0865
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	114 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	146 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8 D9 H4Q U99 H)	
<b>ISOCETYL STEAROYL STEARATE</b> (UNII: IJ V4 L S 38 3 R)	
<b>ISODECYL NEOPENTANOATE</b> (UNII: W6 0 V Y E 24 X C)	
<b>ISOPROPYL PALMITATE</b> (UNII: 8 C R Q 2 T H 6 3 M)	
<b>ISODODECANE</b> (UNII: A8 2 8 9 P 6 8 Y 2)	
<b>ISOHEXADECANE</b> (UNII: 9 1 8 X 1 0 U F 1 E)	
<b>POLYTETRAFLUOROETHYLENE</b> (UNII: E 1 N C 1 J V S 3 0)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7 K 3 W 1 B I U 6 K)	

PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
ALUMINUM OXIDE (UNII: LM26O6933)
STEARIC ACID (UNII: 4ELV7Z65AP)
FERROUS OXIDE (UNII: G7036X8B5H)
MICA (UNII: V8A1AW0880)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
PEG-45/DODECYL GLYCOL COPOLYMER (UNII: 9H0V8CHB0X)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
BENZOIC ACID (UNII: 8SKN0B0MM)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)
SUNFLOWER OIL (UNII: 3W1JG795YI)
POLYAMIDE-3 (12000 MW) (UNII: L7P3YWF22X)
TOCOPHEROL (UNII: R0ZB2556P8)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TRIBEHENIN (UNII: 8OC9U7TQZ0)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67015-0865-1	1 in 1 CARTON	05/02/2019	
1		40 mL in 1 BOTTLE; 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	05/02/2019	03/31/2022

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

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