

EAU THERMALE AVENE 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.

Eau Thermale Avene 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, ISOCETYL STEAROYL STEARATE, ISOPROPYL PALMITATE, ISODECYL NEOPENTANOATE, ISODODECANE, ISOHEXADECANE, PTFE, TRIETHYLHEXANOIN, DICAPRYLYL ETHER, PEG-30 DIPOLYHYDROXYSTEARATE, 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, TOCOPHEROL, TOCOPHERYL GLUCOSIDE, TRIBEHENIN, TRIETHOXYCAPRYLYLSILANE.

Questions or comments?

visit 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

Mineral


Sunscreen Fluid

FRAGRANCE-FREE

For sensitive skin, intolerant skin

PARIS

1.35 FL. OZ. (40 mL)

<p>Drug Facts</p> <p>Active ingredients Purpose TITANIUM DIOXIDE 11.4 %..... Sunscreen ZINC OXIDE 14.6 %..... Sunscreen</p> <p>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.</p> <p>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.</p> <p>Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> <p>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. to 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses. • Children under 6 months: Ask a doctor.</p> <p>Other information • Protect this product from excessive heat and direct sun.</p> <p>Inactive ingredients WATER, COCOCAPRYLATE/CAPRATE, ISOCETYL STEAROYL STEARATE, ISOPROPYL PALMITATE, DODECYL NEOPENTANOATE, ISODODECANE, ISOHEXADECANE, PTFE, TRITHYLOXANOLIN, DICAPRYLYL ETHER, PEG-30 DIPOLYHYDROXYSTEARATE, 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-OH-BUTYL HYDROXYHYDROXYNAMATE, POLYAMIDE-3, SODIUM CHLORIDE, TOCOPHEROL, TOCOPHERYL GLUCOSIDE, TRIBHENYL TRITHIOCAPRYLYLSILANE.</p> <p>Questions or comments? Visit www.avenusa.com or call toll-free 1-866-41-AVENE (28363)</p>	<p>Mineral Sunscreen Fluid Broad spectrum SPF 50+ Face</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 for a natural, matifying finish. For skin intolerant to chemical filters and fragrance. Tested on sensitive skin.</p> <p>PROPERTIES</p> <ul style="list-style-type: none"> • 100% mineral UVA/UVB broad spectrum protection • Pre-occaperyl, a photostable form of Vitamin E, provides powerful antioxidant protection and helps absorb free radicals generated by sun exposure and environmental aggressors • Water-resistant (80 minutes) • Provides hydration, ideal for daily use • Matte finish <p>Fluide minéral Large spectre SPF 50+ Visage</p> <p>Ce soin solaire, sans filtre chimique, est composé de filtres 100 % minéraux UVB/UVA et d'un puissant pouvoir antioxydant.</p> <p>Votre peau est protégée, hydratée par cette texture légère. La pénétration du soin est rapide, le fini est mat.</p> <p>Testé sur les peaux sensibles et intolérantes aux filtres chimiques et aux parfums.</p>	<p>EAU THERMALE Avène</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>Mineral Sunscreen Fluid FRAGRANCE-FREE</p> <p>For sensitive, intolerant skin</p> <p>PARIS 1.3 FL. OZ. / 40 ml</p>	<p>OUR SENSITIVE SKIN EXPERTISE</p> <ul style="list-style-type: none"> • Understanding the skin physiology: Avène Hydrotherapy Center has been providing treatments dedicated to dermatology since 1743. • The science of formulation: unique combination of Avène Thermal Spring Water with its soothing, calming and softening properties and a strict selection of innovative ingredients. • 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. <p>✓ Chemical filter-free ✓ Fragrance-free ✓ Dermatologist tested</p> <p>Formulated to minimize risks of allergic reactions - Non-comedogenic.</p> <p> Pierre Fabre Derma-Cosmétique</p> <p>Laboratoires Dermatologiques Avène 45, place AbelCance 92100 Boulogne - Paris - France</p> <p>Distributed by: Pierre Fabre USA, Inc. Parsippany, NJ 07054 Made in France</p>
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EAU THERMALE AVENE MINERAL SUNSCREEN FLUID SPF 50 PLUS			
titanium dioxide, zinc oxide lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:670 15-0864
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	114 mg in 1 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	146 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		
STEARIC ACID (UNII: 4ELV7Z65AP)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
PEG-45/DODECYL GLYCOL COPOLYMER (UNII: 9H0V8CHB0X)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
BENZOIC ACID (UNII: 8SKN0B0MM)			
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)			
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)			
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			

POLYAMIDE-3 (12000 MW) (UNII: L7P3YWF22X)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TOCOPHEROL (UNII: R0ZB2556P8)
TRIBEHENIN (UNII: 8OC9U7TQZ0)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)
ISOCETYL STEAROYL STEARATE (UNII: IJV4LS383R)
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)
ISODODECANE (UNII: A8289P68Y2)
ISOHEXADECANE (UNII: 918X1OUF1E)
POLYTETRAFLUOROETHYLENE (UNII: E1NC1JVS3O)
EDETATE DISODIUM (UNII: 7FLD91C86K)
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)
DICAPRYLYL ETHER (UNII: 77JZM5516Z)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
WATER (UNII: 059QF0KO0R)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
ALUMINUM OXIDE (UNII: LM26O6933)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67015-0864-1	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)