

**AVENE SOLAIRE UV MINERAL SUNSCREEN SPF 50 PLUS- zinc oxide lotion
Pierre Fabre USA Inc.**

Avene Solaire UV Mineral Sunscreen SPF 50 PLUS

Drug Facts

Purpose

Sunscreen

Active Ingredient

Zinc Oxide 12%

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 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 dry.

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 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.

Other information

Protect this product from excessive heat and direct sun.

Inactive ingredients

AVÈNE THERMAL SPRING WATER, C12-15 ALKYL BENZOATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PROPANEDIOL, JOJOBA ESTERS, TRIDECYL SALICYLATE, METHYLHEPTYL ISOSTEARATE, POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE, NYLON-12, NIACINAMIDE, METHYLPROPANEDIOL, COCO-CAPRYLATE, SILICA, SODIUM CHLORIDE, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, CAPRYLYL GLYCOL, BISABOLOL, ALLANTOIN, ORYZA SATIVA (RICE) BRAN EXTRACT, LECITHIN, PHENYLPROPANOL, HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT, TOCOPHEROL, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, TETRASODIUM GLUTAMATE DIACETATE, ISOSTEARIC ACID, 1,2-HEXANEDIOL, SODIUM HYDROXIDE

Questions or comments?

visit www.aveneusa.com or call toll-free 1-866-41-AVENE (28363)

Principal Display Panel - 50 mL Carton

EAU THERMALE

Avene

SPF 50+

Broad Spectrum

Solaire UV

Mineral Multi-Defense

Sunscreen Fluid

Fragrance-Free

Oil-Free

40-Minute Water Resistance

Sheer, Non-Whitening

For Sensitive Skin

50 ml/1.7 FL. OZ.

Drug Facts	
Active Ingredient	Purpose
ZINC OXIDE 12%	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 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 40 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.	
Other Information • Protect this product from excessive heat and direct sun	
Inactive Ingredients WATER, C12-15 ALKYL BENZOATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, PROPANEDIOL, JOJOBA ESTERS, TRIDECYL SALICYLATE, METHYLHEPTYL ISOSTEARATE, POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE, NYLON-12, NIACINAMIDE, METHYLPROPANEDIOL, COCO-CAPRYLATE, SILICA, AVÈNE THERMAL SPRING WATER, SODIUM CHLORIDE, POLYGLYCERYL-2 DILPOLYHYDROXYSTEARATE, CAPRYL GYCOL, BISABOLOL, ALLANTOIN, ORYZA SATIVA (RICE BRAN) EXTRACT, LECITHIN, PHENYLPROPANOL, HELIANTHUS ANNUUS (SUNFLOWER) EXTRACT, TOCOPHEROL, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, TETRASODIUM GLUTAMATE DIACETATE, ISOSTEARIC ACID, 1,2-HEXANEDIOL, SODIUM HYDROXIDE.	
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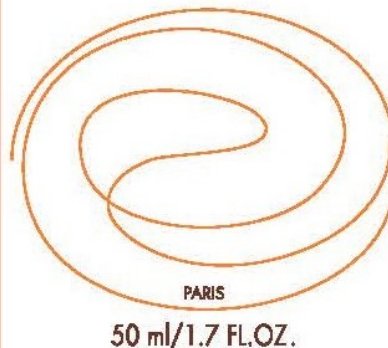
Solaire UV
Mineral Multi-Defense
Sunscreen Fluid SPF 50+
FACE

A physical sunscreen with 100% mineral UVA/UVB filters and powerful antioxidant protection. Lightweight, multi-defense formula defends against UV rays, pollution and blue light. Absorbs quickly into skin without any white residues.
Tested on sensitive skin.

PROPERTIES

- 100% mineral UVA/UVB filter provides broad spectrum protection
- Bisabolol and Allatoin help soothe and calm skin
- Niacinamide calms skin, defends against free radicals and helps skin appear more even
- Plant-derived Squalane hydrates and leaves skin feeling softer
- Powerful Multi-Defense Shield™ complex boosts antioxidant protection by up to 200%¹
- Water resistance 40 minutes
- Ideal for daily use and can be used under make-up

¹In vitro measure of antioxidant activity after being exposed to 2MED of UV.



OUR SENSITIVE SKIN EXPERTISE

- 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.

- ✓ Mineral UV filter
- ✓ Fragrance-free
- ✓ Dermatologist tested

Formulated to minimize risks of allergic reactions. Non-comedogenic.



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Derma-Cosmétique
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Distributed by:
Pierre Fabre USA Inc
Parsippany, NJ 07054

AVENE SOLAIRE UV MINERAL SUNSCREEN SPF 50 PLUS

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64760-724
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ROSEMARY OIL (UNII: 8LGU7VM393)	
LEVOMENOL (UNII: 24WE03BX2T)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
NIACINAMIDE (UNII: 25X51I8RD4)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
PROPANEDIOL (UNII: 5965N8W85T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
JOJOBA OIL (UNII: 724GKU717M)	
METHYLHEPTYL ISOSTEARATE (UNII: 981F40Q9FF)	
NYLON-12 (UNII: 446U8J075B)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALLANTOIN (UNII: 344S277G0Z)	
RICE BRAN OIL (UNII: LZ06K1506A)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
HELIANTHUS ANNUUS WHOLE (UNII: 17S27ZT6KR)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-724-01	1 in 1 CARTON	05/17/2021	
1		50 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 Drug	M020	05/17/2021	11/06/2025

Labeler - Pierre Fabre USA Inc. (117196928)

Revised: 1/2024

Pierre Fabre USA Inc.