

**AVENE MULTI-DEFENSE FLUID- zinc oxide lotion**  
**Pierre Fabre USA Inc.**

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**Avene Multi-Defense Fluid**

***Drug Facts***

***Active ingredient***

Zinc Oxide 12%

***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 broken skin.

***Stop use and ask a doctor if***

- rash occurs.

***Keep out of reach of children.***

If swallowed, call a poison control center or get medical help right away.

***Directions***

Adults and children 6 months and older:

- Apply generously 15 minutes before sun exposure • Reapply: • at least every 2 hours
- after 40 minutes of swimming or sweating • immediately after towel drying • Children under 6 months of age: Ask a doctor • 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 value 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.

### ***Inactive Ingredients***

Water, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Jojoba Esters, Propanediol, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Tridecyl Salicylate, Nylon-12, Niacinamide, Methylpropanediol, Silica, Glycerin, Sodium Chloride, Coco-Caprylate, Polyglyceryl-2 Dipolyhydroxystearate, Caprylyl Glycol, Bisabolol, Allantoin, Oryza Sativa (Rice) Bran Extract, Lecithin, Stearalkonium Hectorite, Polyglyceryl-3 Diisostearate, Polyglyceryl-3 Polyricinoleate, Phenylpropanol, Helianthus Annuus (Sun-ower) Extract, Tocopherol, Rosmarinus Ofcinalis (Rosemary) Leaf Extract, Tetrasodium Glutamate Diacetate, Sodium Hydroxide.

### ***Other Information***

- Protect this product in this container from excessive heat and direct sun.

### ***Questions?***

1-866-41-AVENE (28363)

**Box 338075**

### Drug Facts

#### Active Ingredient

Zinc Oxide 12% ..... Sunscreen

#### 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 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 swallowed, call a poison control center or get medical help right away.

#### Directions

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- Apply generously 15 minutes before sun exposure
  - Reapply: • at least every 2 hours • after 40 minutes of swimming or sweating • immediately after towel drying
  - Children under 6 months of age: Ask a doctor • 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 value 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.

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### Drug Facts

(continued)

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1-866-41-AVENE (28363)

#### MINERAL SUNSCREEN Multi-Defense Fluid

A physical sunscreen with 100% mineral UVA/UVB filter using encapsulated Zinc Oxide and powerful antioxidant protection. Lightweight, multi-defense formula defends against UV rays, pollution and blue light. Tested on sensitive skin.

#### SUNSHINE™ TECHNOLOGY

A filter system that provides broad UVB-UVA-BLUE LIGHT protection.

**Bisabolol and Allantoin:** help soothe and calm skin.

**Niacinamide:** calms skin, helps defend against free radicals and helps skin appear more even.

**Pro-Vitamin E:** helps protect against environmental oxidative stress.

Absorbs quickly into the skin, leaves no white residue on most skin types.

Water resistance 40 minutes.

Ideal for daily use and can be used under makeup.

### EAU THERMALE AVÈNE

Brand recommended by dermatologists\*.

Eau Thermale Avène provides care dedicated to all skin types, even the most sensitive.

Benefiting from the unique properties of Avène Thermal Spring Water, our scientists and dermatologists study the biological mechanisms of the skin and its interactions with its environment to help soothe, protect and restore.

\*study carried out from internal data in over 90 countries and an IQVIA survey in 8 countries in 2021

#### OUR COMMITMENTS EAU THERMALE AVÈNE

www.eau-thermale-avene.com

- Dermatologist-tested
- Tested on sensitive skin
- Non-comedogenic
- Fragrance-free
- Paraben-free
- Oil-free texture
- Formulated to minimize risks of allergic reactions

EAU THERMALE  
**Avène**  
LABORATOIRE DERMATOLOGIQUE

### MINERAL SUNSCREEN

SPF **50+** BLUE LIGHT  
BROAD SPECTRUM SPF50+

### MULTI-DEFENSE FLUID

Daily face protection  
For sensitive skin

SHEER - LIGHTWEIGHT

WATER RESISTANT  
(40 MINUTES)

40 ml e 1.3 fl.oz.

  
Pierre Fabre  
Dermo-Cosmétique

Distributed by:  
Pierre Fabre USA INC.  
Parsippany, NJ, 07054  
Assembled in USA  
www.avenusa.com  
www.eau-thermale-avene.com

## AVÈNE MULTI-DEFENSE FLUID

zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:64760-778
<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	120 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)	
<b>TRIDECYL SALICYLATE</b> (UNII: AZQ08K38Z1)	
<b>NYLON-12</b> (UNII: 446U8J075B)	

<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)
<b>METHYLPROPANEDIOL</b> (UNII: N8F53B3R4R)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>ALLANTOIN</b> (UNII: 344S277G0Z)
<b>STEARALKONIUM HECTORITE</b> (UNII: OLX698AH5P)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>JOJOBA OIL, RANDOMIZED</b> (UNII: 7F0EV20QYL)
<b>POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE</b> (UNII: 687U3PEB2Y)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE</b> (UNII: 9229XJ4V12)
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)
<b>RICE BRAN</b> (UNII: R60QEP13IC)
<b>SOYBEAN LECITHIN</b> (UNII: 1DI56QDM62)
<b>PHENYLPROPANOL</b> (UNII: 0F897O3O4M)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>POLYGLYCERYL-3 DIISOSTEARATE</b> (UNII: 46P231IQV8)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>COCO-CAPRYLATE</b> (UNII: 4828G836N6)
<b>POLYGLYCERYL-3 PENTARICINOLEATE</b> (UNII: 7Q0OK5DOT4)
<b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-778-01	1 in 1 CARTON	05/01/2024	
1		40 mL in 1 TUBE; 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	05/01/2024	

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

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