

**AVENE HYDRANCE MOISTURIZING SPF 30- zinc oxide lotion**  
**Pierre Fabre USA Inc.**

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**Avene Hydrance Moisturizing Sunscreen Lotion SPF 30**

***Drug Facts***

***Active ingredient***

Zinc oxide 10%

***Purpose***

Sunscreen

***Uses***

- helps prevent sunburn.

***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***

Adults and children 6 months and older:

- Apply generously 15 minutes before sun exposure • Reapply: • at least every 2 hours

• Use a water resistant sunscreen if swimming or sweating • 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, Tridecyl Salicylate, Caprylic/Capric Triglyceride, Shea Butter Ethyl Esters, Propanediol, Coco-Caprylate, C13-15 Alkane, Glycerin, Undecane, Methylpropanediol, Polyglyceryl-3 Polyricinoleate, Pyrus Malus (Apple) Fruit Extract, Sodium Chloride, Disteardimonium Hectorite, Isoamyl Laurate, Silica, Tridecane, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Caprylyl Glycol, Bisabolol, Allantoin, Lecithin, Aloe Barbadensis Leaf Juice Powder, Phenylpropanol, Tetrasodium Glutamate Diacetate, Tocopherol, Sodium Hydroxide.

### ***Other Information***

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

### ***Questions?***

1-866-41-AVENE (28363)

1-877-441-2011 (CAN)

**Box 336505**

### Drug Facts

#### Active Ingredient Purpose

Zinc Oxide 10%.....Sunscreen

**Uses** • Helps prevent sunburn

#### 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 swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

Adults and children 6 months and older: • Apply generously 15 minutes before sun exposure • Reapply at least every 2 hours • Use a water resistant sunscreen if swimming or sweating • 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.

#### Other information

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

### Drug Facts (continued) / Info-médicament (suite)

#### Inactive Ingredients Ingrédients inactifs

Water/Eau/Aqua, Tridecyl Salicylate, Caprylic/Capric Triglyceride, Shea Butter Ethyl Esters, Propanediol, Coco-Caprylate, C13-15 Alkane, Glycerin, Undecane, Methylpropanediol, Polyglyceryl-3 Polyricinoleate, Pyrus Malus (Apple) Fruit Extract, Sodium Chloride, Distearidimonium Hectorite, Isoamyl Laurate, Silica, Tridecane, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Caprylyl Glycol, Bisabolol, Allantoin, Lecithin, Aloe Barbadensis Leaf Juice Powder, Phenylpropanol, Tetrasodium Glutamate Diacetate, Tocopherol, Sodium Hydroxide.

#### Questions?

1-866-41-AVENE (28363)(USA)  
1-877-441-2011 (CAN)

Élaboré en vue de minimiser les risques de réactions allergiques - Non comédogène. Formulated to minimize risks of allergic reactions - Non-comedogenic.



**Pierre Fabre**  
Dermo-Cosmétique

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EAU THERMALE  
**Avène**  
LABORATOIRE DERMATOLOGIQUE

## HYDRANCE+

LARGE SPECTRE FPS 30  
BROAD SPECTRUM SPF 30 **30**

**FLUIDE SOLAIRE**  
**HYDRATANT**

Peaux sensibles déshydratées

**8H** HYDRATANT  
MOISTURIZING

**MOISTURIZING SUNSCREEN**  
**LOTION**

Dehydrated, sensitive skin

NPN 80124824 40 ml e  
1.3 fl.oz.

### Info-médicament

#### Ingrédient actif Utilité

Oxyde de zinc 10 %.....Écran solaire

**Usages** • Aide à prévenir les coups de soleil

#### Mises en garde

Pour usage externe seulement.

**Ne pas utiliser** • sur une peau éraflée.

**Lorsque vous utilisez ce produit** • éviter tout contact avec les yeux. Le cas échéant, bien rincer avec de l'eau.

**Cessez d'utiliser le produit et consultez un médecin si** • une éruption cutanée se développe.

**Garder hors de portée des enfants.** En cas d'ingestion, appeler immédiatement un centre antipoison ou obtenir une assistance médicale.

#### Mode d'emploi

Adultes et enfants de 6 mois et plus : • Appliquer généreusement 15 minutes avant l'exposition au soleil • Appliquer de nouveau au moins toutes les deux heures • Utiliser une protection solaire résistante à l'eau en cas de baignade ou transpiration • Enfants de moins de 6 mois: Consulter un médecin, • **Mesures 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 et 14 heures • porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil.

#### Autre renseignement

• Ne pas exposer ce produit à des températures excessives ou au soleil.

## AVENE HYDRANCE MOISTURIZING SPF 30

zinc oxide lotion

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:64760-783 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 100 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)                                       |          |
| COCO-CAPRYLATE (UNII: 4828G836N6)  |          |
| C13-15 ALKANE (UNII: 114P5I43UJ)   |          |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)                                 |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)   |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)   |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)   |          |
| WATER (UNII: 059QF0KO0R)   |          |
| TOCOPHEROL (UNII: R0ZB2556P8)  |          |
| METHYLPROPANEDIOL (UNII: N8F53B3R4R)   |          |
| SHEA BUTTER ETHYL ESTERS (UNII: V2CI786FPG)                                  |          |
| PROPANEDIOL (UNII: 5965N8W85T)   |          |
| POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y) |          |
| GLYCERIN (UNII: PDC6A3C0OX)  |          |
| POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q00K5DOT4)                           |          |
| APPLE (UNII: B423VGH5S9)   |          |
| ALLANTOIN (UNII: 344S277G0Z)   |          |
| PHENYLPROPANOL (UNII: 0F897O3O4M)  |          |
| TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)                           |          |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)  |          |
| TRIDECANE (UNII: A3LZF0L939)   |          |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                                |          |
| UNDECANE (UNII: JVOQT00NUE)  |          |
| ISOAMYL LAURATE (UNII: M1SLX00M3M)   |          |
| LEVOMENOL (UNII: 24WE03BX2T)   |          |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62)   |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)  |          |

## Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:64760-783-01 | 1 in 1 CARTON                                      | 04/01/2024           |                    |
| 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                                     | 04/01/2024           |                    |

