

AVENE FACE SUNSCREEN SPF 50- zinc oxide lotion
Pierre Fabre USA Inc.

Avene Face Lotion SPF 50

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.

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
- after 80 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/Eau/Aqua, Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Glycerin, Tridecyl Salicylate, Polyglyceryl-3 Polyricinoleate, Glyceryl Stearate, Shea Butter Ethyl Esters, Sodium Chloride, Polyester-7, Silica, Neopentyl Glycol Diheptanoate, Isoamyl Laurate, Polyglyceryl-2 Dipolyhydroxystearate, Glyceryl Dibehenate, Bisabolol, Phenylpropanol, Iron Oxides, Propanediol, Lecithin, Tribehenin, Allantoin, Caprylyl Glycol, Glyceryl Behenate, Coco-Caprylate, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Polyglyceryl-4 Diisostearate/ Polyhydroxystearate/Sebacate, Hydrogenated Lecithin, Sodium Hydroxide, Tocopherol.

Other information

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

Questions?

1-866-41-AVENE (28363)

1-877-441-2011 (CAN)

Box 337120

Drug Facts

Active Ingredient Purpose
Zinc Oxide 12%.....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 • after 80 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.

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, Caprylic/Capric Triglyceride, C12-15 Alkyl Benzoate, Glycerin, Tridecyl Salicylate, Polyglyceryl-3 Polyricinoleate, Glyceryl Stearate, Shea Butter Ethyl Esters, Sodium Chloride, Polyester-7, Silica, Neopentyl Glycol Diheptanoate, Isoamyl Laurate, Polyglyceryl-2 Dipolyhydroxystearate, Glyceryl Dibehenate, Bisabolol, Phenylpropanol, Iron Oxides, Propanediol, Lecithin, Tribehenin, Allantoin, Caprylyl Glycol, Glyceryl Behenate, Coco-Caprylate, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Polyglyceryl-4 Diisostearate/ Polyhydroxystearate/ Sebacate, Hydrogenated Lecithin, Sodium Hydroxide, Tocopherol.

Questions?

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

Teinte naturelle - Nude tint.

Pour un fini transparent sans trace blanche - To offset whitencast.

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

Import. by/par:
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Fabriqué aux États-Unis / Assembled in USA
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EAU THERMALE
Avène
LABORATOIRE DERMATOLOGIQUE

MINERAL SUNSCREEN

SPF **50** BLUE LIGHT
LARGE SPECTRE / BROAD SPECTRUM SPF50

FLUIDE VISAGE

Peaux sensibles
Enfants & adultes

FACE LOTION

Sensitive skin
Children & adults

RÉSISTANT À L'EAU (80 MINUTES)
WATER RESISTANT (80 MINUTES)



40 ml e
1.3 fl.oz.

Info-médicament

Ingrédient actif Utilité
Oxyde de zinc 12%.....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 • après 80 minutes de baignade ou après avoir transpiré • immédiatement après s'être séché à la serviette • 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 FACE SUNSCREEN SPF 50

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64760-782
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
LEVOMENOL (UNII: 24WE03BX2T)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
ALLANTOIN (UNII: 344S277G0Z)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
WATER (UNII: 059QF0KO0R)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYESTER-7 (UNII: 0841698D2F)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
PROPANEDIOL (UNII: 5965N8W85T)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
SHEA BUTTER ETHYL ESTERS (UNII: V2CI786FPG)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-782-01	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)

Revised: 3/2024

Pierre Fabre USA Inc.