AVENE MINERAL SUNSCREEN FACE AND BODY- 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.

Avene Mineral Sunscreen Face & Body Lotion SPF 50

Drug Facts

Purpose

Sunscreen

Active Ingredient

Zinc Oxide 12%

Uses

helps prevent sunburn.

if used as directed with other sun protection measures (see Directions), decreased 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

Apply generously 15 minutes before sun exposure.

Reapply:
- after 80 minutes of swimming or sweating.
- immediately after towel drying.
- at least every 2 hours.
- children under 6 months of age: Ask a doctor.

Sun Protection Measures. Spending time in te 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 this product from excessive heat and direct sun.

Inactive Ingredients

Allantoin, avene thermal spring water (avene aqua), bisabolol, C12-C15 alkyl benzoate, caprylic/capric triglyceride, caprylyl glycol, coco-caprylate, glycerin, glyceryl behenate, glyceryl dibehenate, glyceryl stearate, isoamyl laurate, lecithin, methylpropanediol, neopentyl glycol diheptanoate, phenylpropanol, polyester-7, polyglyceryl-3 polricinoleate, polyglyceryl-4 diisostearate/polyhydroxystearate/sebacate, silica, sodium chloride, tocopherol, tocopheryl acetate, tribehenin, tridecyl salic

Questions?

1-866-41-AVENE (28363)

Package Label

EAU THERMALE

AVENE

LABORATORIE DERMATOLOGIQUE

MINERAL SUNSCREEN

SPRF 50 UVA-UVB

BROAD SPECTRUM SPF50

FACE & BODY LOTION

FOR SENSITIVE SKIN

CHILDREN & ADULTS

LIGHTWEIGHT TEXTURE

FAST-ABSORPTION

WATER-RESISTANT (80 MINUTES)

125ML 4.2 FL.OZ.

AVENE MINERAL SUNSCREEN FACE AND BODY

zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64760-780

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 120 mg

Inactive Ingredients

Ingredient Name	Strength
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POLYESTER-7 (UNII: 0841698D2F)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
GLYCERYL BEHENATE/EICOSADIOATE (UNII: 73CJJ317SR)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE (UNII: 687U3PEB2Y)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LEVOMENOL (UNII: 24WE03BX2T)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-780-01	1 in 1 CARTON	06/26/2023	
1		120 mg 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 final	M020	05/17/2023	

Labeler - Pierre Fabre USA Inc. (117196928)

Registrant - Pierre Fabre USA Inc. (117196928)

Revised: 5/2023 Pierre Fabre USA Inc.