

SAGE AND ZINC FACIAL HYDRATING SPF 15- zinc oxide cream
Emeis Cosmetics Pty Ltd

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.

Aēsop®
Sage & Zinc Facial Hydrating Cream with Sunscreen

Drug Facts

Active ingredient

Zinc Oxide 16.1%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

For external use only.

Do not use on damaged or broken skin.

Stop use and ask a doctor if rash occurs.

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months of age: Ask a doctor

Other information

- Protect the product in this container from excessive heat and direct sun.
- You may report a serious adverse reaction to Report Reaction LLC, PO Box 22, Plainsboro, NJ 08536-0222.

Inactive ingredients

Water, Caprylic/Capric Triglyceride, PEG-100 Stearate, Glycerin, Cetearyl Alcohol, Potassium Cetyl Phosphate, Macadamia Ternifolia Seed Oil, Squalane, Hydrogenated Palm Glycerides, Phenoxyethanol, Tocopheryl Acetate, Lauryl Pyrrolidone, Oenothera Biennis (*Evening Primrose*) Oil, Silica, Citric Acid, Lavandula Angustifolia (*Lavender*) Oil, 1,2-Hexanediol, Salvia Officinalis (*Sage*) Oil, Tocopherol, Disodium EDTA, Xanthan Gum, Glycine Soja (*Soybean*) Oil, Fusanus Spicatus Wood Oil, Caprylyl Glycol, Magnesium Aluminum Silicate, Ethylhexylglycerin, Glycine Soja (*Soybean*) Seed Extract, Daucus Carota Sativa (*Carrot*) Root Extract, Beta-Carotene.

Manufactured in Australia.

Aesop, 25 Smith Street, Fitzroy 3065 Australia.

PRINCIPAL DISPLAY PANEL - 47 g Tube Carton

Aēsop®

**Sage & Zinc Facial Hydrating Cream with Sunscreen
SPF
15**

Zinc Oxide • Tocopheryl Acetate • Sage Leaf

Daily moisturising sunscreen SPF15 for all skin types. A hydrating blend of superior botanicals including Sage Leaf and Sandalwood, with the benefits of Zinc Oxide.

Massage evenly over the face from forehead to neck after cleansing and reapply during the day to maintain protection. Enhanced with plant-derived vitamins including Vitamin E, this cream with mineral-based sunscreen is ideal for city living.

www.aesop.com

Net Wt. 47 g / 1.6 Oz.

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Aesop, 25 Smith Street, Fitzroy 3065 Australia.

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US: Aesop USA Inc., P.O. Box 8045, New York, NY 10150

PB408K37B.01



BATCH

Drug Facts (continued)

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Aēsop®

Sage & Zinc Facial Hydrating Cream with Sunscreen
Crème Hydratante à la Saugé et au Zinc pour le Visage

SPF
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Aēsop®

Crème Hydratante à la Saugé et au Zinc pour le Visage
Sage & Zinc Facial Hydrating Cream with Sunscreen

SPF
15

Oxyde de Zinc • Acétate de Tocophéryle • Feuille de Saugé

Crème hydratante de jour avec indice de protection 15 pour tous types de peaux. Un mélange hydratant de plantes de qualité dont la Feuille de Saugé et le Bois de Santal, et d'Oxyde de Zinc protecteur.

Crème hydratante de jour avec indice de protection 15 pour tous types de peaux. Un mélange hydratant de plantes de qualité et d'Oxyde de Zinc protecteur.

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Net Wt. 47 g / 1.6 Oz.

SAGE AND ZINC FACIAL HYDRATING SPF 15

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76293-037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.26 g in 1.54 g

Inactive Ingredients

Ingredient Name	Strength
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Water (UNII: 059QF0KO0R)	
PEG-100 Stearate (UNII: YD01N1999R)	
Glycerin (UNII: PDC6A3C0OX)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)	
Macadamia Oil (UNII: 515610SU8C)	
Squalane (UNII: GW89575KF9)	
Hydrogenated Palm Glycerides (UNII: YCZ8EM144Q)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
.Alpha.-Tocopherol Acetate, DL- (UNII: WR1WPI7EW8)	
Lauryl Pyrrolidone (UNII: 3P14VW8FNY)	
Evening Primrose Oil (UNII: 3Q9L08K71N)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Lavender Oil (UNII: ZBP1YXW0H8)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
Sage Oil (UNII: U27K0H1H2O)	
Tocopherol (UNII: R0ZB2556P8)	
Edetate Disodium (UNII: 7FLD91C86K)	
Xanthan Gum (UNII: TTV12P4NEE)	
Soybean Oil (UNII: 241ATL177A)	
Santalum Spicatum Oil (UNII: H9LVS6REV4)	
Caprylyl Glycol (UNII: 00YIU5438U)	
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Soybean (UNII: L7HT8F1ZOD)	
Carrot (UNII: L56Z1JK48B)	
Beta Carotene (UNII: 01YAE03M7J)	

Product Characteristics

Color	YELLOW (Pale yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76293-037-56	12 in 1 CARTON		
1	NDC:76293-037-74	71 g in 1 JAR		
2	NDC:76293-037-63	24 in 1 CARTON		
2	NDC:76293-037-42	47 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	02/01/2012	

Labeler - Emeis Cosmetics Pty Ltd (754271146)

Revised: 11/2011

Emeis Cosmetics Pty Ltd