MINERAL SPF 40 MOISTURIZER- zinc oxide and titanium dioxide lotion Mineral Fusion brands

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.

Mineral SPF 40 Moisturizer

Drug Facts

Active Ingredients	Purpose	
Titanium Dioxide 7.5%	Sunscreen	
Zinc Oxide 5.0%	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 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 liberally to clean skin 15 minutes before sun exposure
- Reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **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 of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

Mineral Water (Aqua), Aloe Barbadensis (Aloe Vera) Leaf Juice¹ Caprylic/Capric Triglyceride, Ethylhexyl Palmitate, Glyceryl Stearate, Cetyl Dimethicone, Vegetable Glycerin, Hexyl Laurate, Polyglyceryl-4 Isostearate, Cetyl Alcohol, Myristyl Myristate, Simmondsia Chinensis (Jojoba) Seed Oil¹ Butyrospermum Parkii (Shea) Butter¹, Panthenol, Malachite Extract, Smithsonite Extract, Rhodochrosite Extract, Hematite Extract, Palmitoyl Pentapeptide-3, Cucumis Sativus (Cucumber) Fruit Extract¹, Tocopherol Acetate, Allantoin, Soy Lecithin, Camellia Sinensis (Green Tea) Leaf Extract¹, Sodium PCA, Hyaluronic Acid, Chamomilla Recutita (Matricaria) Flower Extract¹, Rosmarinus Officinalis (Rosemary) Leaf Oil, Calendula Officinalis Flower Extract¹, Cedrus Atlantica (Cedarwood) Bark Oil, Ginkgo Biloba Leaf Extract¹, Alaria Esculenta (Sea Kelp) Extract, Pelargonium Graveolens (Geranium) Flower Oil, Magnesium Aluminum Silicate, Benzyl Alcohol, Ethylhexylglycerin, Phenoxyethanol, Natural Fragrance.

1 Certified Organic

Questions

Call 1-800-428-1668 Mon-Fri 8 a.m. – 5 p.m. PST

Dist. by Mineral Fusion Petaluma, CA 94954 USA

PRINCIPAL DISPLAY PANEL - 96 g Tube Carton

Mineral SPF 40 Moisturizer

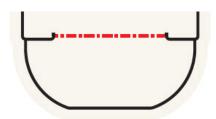
Nourishing Hydration with Shea Butter Broad Spectrum

MINERAL FUSION®

Making Beauty Healthy®

Net Wt 3.4 oz e 96 g





MINERAL SPF 40 MOISTURIZER

zinc oxide and titanium dioxide lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55789-3109

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 g in 100 mL		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7.5 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SHEA BUTTER (UNII: K49155WL9Y)	
PANTHENOL (UNII: WV9CM0O67Z)	
MAGNESIUM ASPARTATE (UNII: R17X820ROL)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
JOJOBA OIL (UNII: 724GKU717M)	
TOCOPHEROL (UNII: ROZB2556P8)	
COPPER GLUCONATE (UNII: RV823G6G67)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALLANTOIN (UNII: 344S277G0Z)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 4690TG57A2)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55789- 3109-2	1 in 1 CARTON	09/17/2019		
1		60 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 NOT FINAL	part352	12/10/2012			

Labeler - Mineral Fusion brands (831770032)

Revised: 9/2019 Mineral Fusion brands