MINERAL SUNSCREEN SPF-30- titanium dioxide, zinc oxide liquid NEWCO LLC

ELIXIR Mineral Sunscreen Spray SPF-30

Drug Facts

Active Ingredient

Titanium Dioxide 6.00% Zinc Oxide 6.00%

Purpose

Sunscreen

Uses:

• Helps prevent sunburn. • Higher SPF gives more sunburn protection. • Retains SPF after 80 minutes of swimming or sweating. • 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 consult your doctor

if a rash or irritation occurs.

Keep out of reach of children.

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

If pregnant or breast-feeding,

ask a health professional before use.

Directions:

• Apply liberally 15 minutes before sun exposure and as needed. • Children under 6 months of age: Ask a doctor. • After 80 minutes of swimming or sweating. • Immediately after towel drying. • At least every 2 hours. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with 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-sleeved shirts, pants, hats, and sunglasses.

Reapply:Sun Protection Measures:

Other Information

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

Other Ingredients:

*Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), *Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Caprylyl/Capryl Glucoside, *Carthamus Tinctorius (Safflower) Oil, Ethylhexylglycerin, *Glycerin, Glyceryl Stearate Citrate, *Helianthus Annuus (Sunflower) Oil, Lecithin, Phenoxyethanol, Polyhydroxystearic Acid, *Punica Granatum (Pomegranate) Extract, Stearic Acid, Tetrasodium Glutamate Diacetate, *Theobroma Cacao (Cocoa) Butter, Tocopherol (Vitamin E), Xanthan Gum.

*Denotes organic ingredients

Package Labeling:



MINERAL SUNSCREEN SPF-30

titanium dioxide, zinc oxide liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83387-399

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
COCOA (UNII: D9108TZ9KG)	
TOCOPHEROL (UNII: ROZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:83387-399-00	177 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/17/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	04/17/2023		

Labeler - NEWCO LLC (117874606)

Revised: 11/2023 NEWCO LLC