

PREVENTION SUN SERUM SPF30- zinc oxide cream

Allure Labs

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.

Drug Facts

Active ingredient

Zinc Oxide 15.6%

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 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

Shake well before use • apply generously 15 minutes before sun exposure • children under 6 months of age: Ask a doctor • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • 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.-2 p.m. • wear long-sleeved shirts, pants, hats and sunglasses

Other information • protect the product in this container from excessive heat and direct sun

Inactive ingredients:

ISODODECANE, SQUALANE, POLYSILICONE-11, PROPANEDIOL DICAPRYLATE/CAPRATE, POLYGLYCERYL-3 POLYRICINOLEATE, POLYHYDROXYSTEARIC ACID, TRIETHOXYCAPRYLYLSILANE, LECITHIN, TOCOPHERYL ACETATE, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL ZINGIBER OFFICINALE (GINGER) ROOT EXTRACT, LIMONENE, CAMELLIA OLEIFERA SEED OIL, TETRAHEXYLDECYL ASCORBATE, PRUNUS ARMENIACA (APRICOT) KERNEL OIL, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, ALOE BARBADENSIS LEAF EXTRACT, CITRAL, LINALOOL, CITRIC ACID.

<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> <tr> <td>Zinc Oxide 15.6%</td> <td>Sunscreen</td> </tr> </table> <p>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</p> <p>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.</p> <p>Directions • shake well before use • apply generously 15 minutes before sun exposure • children under 6 months of age: Ask a doctor • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating • 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.-2 p.m. • wear long-sleeved shirts, pants, hats and sunglasses</p> <p>Other information • protect the product in this container from excessive heat and direct sun</p> <p>Inactive ingredients ISODODECANE, SQUALANE, POLYSILICONE-11, PROPANEDIOL DICAPRYLATE/CAPRATE, POLYGLYCERYL-3 POLYRICINOLEATE, POLYHYDROXYSTEARIC ACID, TRIETHOXYCAPRYLSILANE, LECITHIN, TOCOPHERYL ACETATE, CITRUS AURANTIUM DULCIS (ORANGE) PEEL OIL, ZINGIBER OFFICINALE (GINGER) ROOT EXTRACT, LIMONENE, CAMELLIA OLEIFERA SEED OIL, TETRAHEXYLDECYL ASCORBATE, PRUNUS ARMENIACA (APRICOT) KERNEL OIL, CARTHAMUS TINCTORIUS (SAFFLOWER) SEED OIL, ALOE BARBADENSIS LEAF EXTRACT, CITRAL, LINALOOL, CITRIC ACID.</p> <p>Questions? call 800-796-7546</p> <p>Manufactured for IMAGE Skincare Lantana, FL 33462 USA Manufactured in USA from globally sourced ingredients and components. www.ImageSkincare.com</p>	Active ingredient	Purpose	Zinc Oxide 15.6%	Sunscreen	<p>clean clinical skincare™</p> <p>PHYSICIAN-FORMULATED</p> <p>Tried, true and tested by skincare professionals</p> <ul style="list-style-type: none"> A mineral SPF 30 sunscreen serum that provides broad-spectrum UV protection with a featherweight, dewy finish Innovative formula features an all-mineral UV filter in a hydrating serum texture for daily use Plant-derived squalane from sugarcane helps to moisturize the skin Formulated with antioxidants ginger root extract, vitamin C and vitamin E Chamomile helps to soothe the skin <p>PREVENTION+ sun serum SPF 30</p> <p>pure mineral UV filter</p> <p>broad spectrum SPF 30 sunscreen</p> <p>Net wt. 1 oz / 28.3 g</p> <p>PETA APPROVED Global Animal Test Policy</p> <p>CRUELTY FREE PSC 141</p>	<p>IMAGE SKINCARE</p> <p>Multi-action daily sun care to fight environmental skin stressors</p> <p>Smooth blending, moisturizing formula defends against dryness and other signs of premature skin aging</p>
Active ingredient	Purpose					
Zinc Oxide 15.6%	Sunscreen					

PREVENTION SUN SERUM SPF30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4225
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ORANGE OIL (UNII: AKN3KSD11B)	
GINGER (UNII: C5529G5JPQ)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CITRAL (UNII: T7EU0O9VPP)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
ISODODECANE (UNII: A8289P68Y2)	

DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
SAFFLOWER OIL (UNII: 65UEH262IS)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
SQUALANE (UNII: GW89575KF9)
CAMELLIA OIL (UNII: T1PE06G0VE)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
PROPANEDIOL DICAPRYLATE/CAPRATE (UNII: F53961BX4F)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
APRICOT KERNEL OIL (UNII: 54JB35T06A)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4225-1	7 g in 1 TUBE; Type 0: Not a Combination Product	01/05/2023	
2	NDC:62742-4225-3	1 in 1 CARTON	01/05/2023	
2	NDC:62742-4225-2	28.3 g 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	01/05/2023	

Labeler - Allure Labs (926831603)

Registrant - Allure Labs (926831603)

Establishment			
Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4225)