

QUENCH AND PROTECT HYDRATING SPF30- zinc dioxide and titanium dioxide 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 INGREDIENTS:

Zinc Oxide - 6.0%

Titanium Dioxide 4.7%

Purpose: Sunscreen

Uses: Helps prevent sunburn. If used as directed with other sun protection measures, this product decreases the risk of skin cancer and early skin aging caused by the sun.

Warning:

For external use only

Do not use on damage or broken skin.

When using this product keep out of eye. 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.

Direction:

Apply liberally 15 minutes before sun exposure.

Children under 6 month of age: Ask a doctor

Reapply 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 value of 15 or higher and other sun protection measures including: Limit time in the sun < especially from 10 am - 2.0 pm, Wear long - sleeved shirts, pants, hats and sunglasses.

Other Information:

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

INACTIVE INGREDIENT: Water, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Dimethicone, Cyclohexasiloxane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Aluminum Hydroxide, Stearic Acid, Glycerin, Cetearyl Oliviate, Hexyl Laurate, Sodium Chloride, Pichia/ Resveratrol, Ferment Extract, Sorbitane Oliviate, Dimethicone/Polyglycerin -3 Crosspolymer, Polyglyceryl-4 Isostearate, Panthenol, Cetyl PEG/PPG-10/1 Dimethicone, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Venyl Dimethicone, Crosspolymer, Sodium Hyaluronate,

Phenoxyethanol, Caprylyl Glycol, Ethylhexylglycerin, Hexylene Glycol, Fragrance, Tocopheryl Acetate.



QUENCH AND PROTECT HYDRATING SPF30

zinc dioxide and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62742-4230
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
WATER (UNII: 059QF0KO0R)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
PRUNUS PERSICA SEED (UNII: V9C81470RR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
RESVERATROL (UNII: Q369O8926L)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PANTHENOL (UNII: WW9CM0O67Z)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
TRIETHOXYSIYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CYCLOMETHICONE 7 (UNII: KCK5L8VU47)	
DIMETHICONE/POLYGLYCERIN-3 CROSSPOLYMER (UNII: 2P2G24V6T9)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62742-4230-2	1 in 1 CARTON	08/23/2023	
1	NDC:62742-4230-1	57 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	08/23/2023	

Labeler - Allure Labs. (926831603)

Registrant - Allure Labs (926831603)

Establishment

Name	Address	ID/FEI	Business Operations
Allure Labs		926831603	manufacture(62742-4230)

Revised: 8/2023

Allure Labs.