

COVERQUEEN ALL IN ONE SUN ROLL- zinc oxide, titanium dioxide, niacinamide, adenosine cream
SKINFARM

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

Zinc Oxide, Titanium Dioxide, Niacinamide, Adenosine

Water, Propylheptyl Caprylate, Acrylates Copolymer, Butyloctyl Salicylate, Dicaprylyl Ether, Butylene Glycol, Dicaprylate/Dicaprate, Disiloxane, Propanediol, Polyglyceryl-4 Diisostearate/Polyhydroxystearate/Sebacate, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Silica, Dimethicone, Aluminum Hydroxide, Stearic Acid, Triethoxycaprylylsilane, Cetyl PEG/PPG-10/1 Dimethicone, Ethylhexylglycerin, Disteardimonium Hectorite, Magnesium Sulfate, 1,2-Hexanediol, Disodium EDTA, Fragrance, Citral, Citronellol, Limonene, Hexyl Cinnamal, Hydroxycitronellal, Linalool, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde,

Helps prevent sunburn*if used as directed with other sun protection measures (see under Directions), decreases the risk of skin cancer and early skin aging by the sun

KEEP OUT OF REACH OF THE CHILDREN

Directions

*Apply liberally 15 minutes before sun exposure

*Apply all skin will be exposed to the sun

*Reapply *after 80 minutes of swimming or sweating *immediately after towel drying

*at least every 2 hours

*children under the age of 6 months of age: ask a Doctor

*Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: *limit time in the sun, especially from 10 AM to 2 PM *wear long-sleeve shirts, pants, hats, and sunglasses

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 or redness occurs

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

Other information

*do not store this product under the direct sun light or the excessive heat

*may stain some fabrics or surfaces

external use only



COVERQUEEN ALL IN ONE SUN ROLL

zinc oxide, titanium dioxide, niacinamide, adenosine cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:73793-0013 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| ADENOSINE (UNII: K72T3FS567) (ADENOSINE - UNII:K72T3FS567) | ADENOSINE | 0.04 g in 100 g |
| NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4) | NIACINAMIDE | 2 g in 100 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 7 g in 100 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 13 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------|----------|
| WATER (UNII: 059QF0KO0R) | |

DIMETHICONE (UNII: 92RU3N3Y1O)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:73793-0013-1 | 40 g in 1 BOTTLE; Type 0: Not a Combination Product | 03/01/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 03/01/2021 | |

Labeler - SKINFARM (688594873)

Registrant - SKINFARM (688594873)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------|---------|-----------|-------------------------|
| SKINFARM | | 688594873 | manufacture(73793-0013) |

Revised: 3/2021

SKINFARM