

**PREQUEL SUN BARRIER MINERAL SUNSCREEN BROAD SPECTRUM SPF 50-
mineral sunscreen cream
The Center Brands, LLC**

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 18%

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.

Directions

- apply generously 15 minutes before sun exposure
- 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
- children under 6 months of age: Ask a doctor

Inactive ingredients

Water (Aqua), Caprylic/Capric Triglyceride, Diisooctyl Succinate, Butyloctyl Salicylate, Propanediol, Glycerin, Cetearyl Oliviate, Polyhydroxystearic Acid, Sorbitan Oliviate,

Polyhydroxystearic Acid, Sorbitan Olivat, Bisabolol, Pongamia Pinnata Seed Extract, Zingiber Officinale Root Extract, Tetrahydrodiferuloylmethane, Tetrahydrodemethoxydiferuloylmethane, Tetrahydrodemethoxydiferuloylmethane, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita Flower Extract, Centella Asiatica Extract, Phenoxyethanol, Polyglyceryl-4 Laurate/Succinate, Lauroyl Lysine, Triethoxycaprylylsilane, Arachidyl Alcohol, Silica, Xanthan Gum, Potassium Cetyl Phosphate, Behenyl Alcohol, Caprylyl Glycol, VP/Eicosene Copolymer, Arachidyl Glucoside, Tetrasodium Glutamate Diacetate, Ethylhexylglycerin, Tocopheryl Acetate, Cetyl Alcohol, Tin Oxide, Isononyl Isononanoate, Ethylene/Propylene/Styrene Copolymer, Sorbitan Oleate, Titanium Dioxide (CI 77891), Mica (CI 77019), Iron Oxides (CI 77499, CI 77491)

Other Information

- protect the product in this container from excessive heat and direct sun

Questions?

Visit prequelskin.com

Principal Display Panel

DATE SUBMITTED: 8.14.23
 BRAND NAME: PREQUEL
 PRODUCT NAME: SPF MINERAL UC

PRINTING SPECS/FINISHES/VARNISHES:
 MATTE AQ, 2 PMS, BLACK, KO WHITE
 SPECIAL NOTES:
 DIE - THECENTER_23066-01_C.EPS
 PART #020-00316

DECO COLOR COUNT:



DOES NOT PRINT:



THE CENTER

6⁹/₃₂

PART 020-00316

9¹/₃₂

YOUR SKIN TELLS YOUR STORY

Prequel.

Prequel.

SUN BARRIER MINERAL SUNSCREEN BROAD SPECTRUM SPF 50 PA++++

FAST-ABSORBING, MOISTURIZING SUNSCREEN WITH AN ULTRA-SHEER FINISH

18% ZINC OXIDE, BIOACTIVE ANTIOXIDANT COMPOUNDS + BISABOLOL

pH 7.5 ±

1.7 FL. OZ / 50 ML

KEY DERMATOLOGICAL INGREDIENTS

- **BIOACTIVE ANTIOXIDANT COMPOUNDS**
Tetrahydrocurcuminoids that scavenge free radicals, reduce irritation and increase skin brightness
- **PONGAMIA**
High purity, photostable extract that helps reduce skin stress after UV exposure and environmental aggressors
- **BISABOLOL, CALENDULA + CENTELLA ASIATICA**
Reduce the appearance of redness and provide skin relief

SKINCARE TECHNOLOGY

LAMELLAR PHASE EMULSION

- A. Structurally similar to intercellular skin lipids
- B. Supports the skin barrier to help guard against irritants
- C. Reduces moisture loss and promotes luminescence

8 10129 11004 3

SUN BARRIER MINERAL SUNSCREEN BROAD SPECTRUM SPF 50 PA++++

A sheer, lightweight mineral sunscreen that provides optimal physical protection while boosting the skin's moisture barrier. Formulated with zinc oxide, bioactive antioxidant compounds and bisabolol, this product absorbs easily while soothing and protecting the skin from environmental stressors. Peachy hue blends seamlessly and neutralizes white cast for an ultra-sheer, natural and supple finish.

NON-GREASY
FRAGRANCE-FREE
HYPOALLERGENIC
ALLERGY-TESTED
SUITABLE FOR ALL SKIN TYPES
SAFE FOR SENSITIVE SKIN
SAFE FOR ECZEMA PRONE SKIN
DERMATOLOGIST-DEVELOPED
DERMATOLOGIST-TESTED

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 18.0%	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. When using this product keep out of eyes. Rinse with water to remove. Do not use on - damaged or broken skin. - 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.

Directions
 Apply liberally and evenly 15 minutes before sun exposure. Sun Protection Measures: Spending time in the sun increases risk of skin cancer and early 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 10:00 a.m. - 2:00 p.m. - Wear long sleeved shirts, pants, hats, and sunglasses - Reapply at least every 2 hours - Use a water resistant sunscreen if swimming or sweating - Children under 6 months: ask a doctor.

Other Information
 Protect this product from excessive heat and direct sun.

Inactive Ingredients
 Water (Aqua), Caprylic/Capric Triglyceride, Dimethyl Siloxane, Polybutyl Methacrylate, Propylhexanediol, Glyceryl Stearate, Cetearyl Alcohol, Polyhydroxyester Acid, Sorbitan Oleate, Butylglycol, Pongamia Seed Extract, Zingiber Officinale Root Extract, Tetrahydrodiferuloylmethane, Tetrahydrodimerethoxydiferuloylmethane, Tetrahydrodimerethoxydiferuloylmethane, Calendula Officinalis Flower Extract, Carnella Sherata Leaf Extract, Chamomilla Recutita Flower Extract, Carnella Ailakia Extract, Phenoxyethanol, Polyglyceryl-4 Laurate/Succinate, Lauryl Lysine, Triethoxypropylsilane, Acetyl Glucoside, Silica, Xanthan Gum, Potassium Citrate, Phospholipids, Alcohol, Caprylyl Glycol, VP/Eicosane Copolymer, Arachidyl Dimethyl Sulfoniolammonium Chloride, Ethylhexylglycerin, Triethoxyacetate, Capryl Alcohol, Tin Dioxide, Isotriazolinone, Tetrahydrodimerethoxypropylene Copolymer, Sorbitan Oleate, Titanium Dioxide (CI 77891), Mica (CI 77019), Iron Oxides (CI 77499, CI 77491).

Questions?
 Visit prequelskin.com

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PREQUEL SUN BARRIER MINERAL SUNSCREEN BROAD SPECTRUM SPF 50

mineral sunscreen cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82800-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CAPRYLIC/CAPRIC MONO/DI-GLYCERIDES (UNII: U72Q2I8C85)	
DIISOCETYL ADIPATE (UNII: 14885YC9LU)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
.BETA.-BISABOLOL (UNII: LP618AV2EA)	
PONGAMIA PINNATA SEED (UNII: C2BRV53B1V)	
ZINGIBER OFFICINALE WHOLE (UNII: IN6Q3S3414)	
TETRAHYDRODIFERULOYLMETHANE (UNII: 00U0645U03)	
TETRAHYDRODEMETHOXYDIFERULOYLMETHANE (UNII: 44D8X9U00T)	
TETRAHYDROBISDEMETHOXYDIFERULOYLMETHANE (UNII: 973IBV8W7I)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAMELLIA SINENSIS SEED (UNII: MRL49Z8AC4)	
MATRICARIA CHAMOMILLA FLOWERING TOP (UNII: 3VNC7T6Z02)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 LAURATE/SUCCINATE (UNII: KAB6DS9SBS)	
LAUROYL LYSINE (UNII: 113171Q70B)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
SILICON (UNII: Z4152N8IU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
ARACHIDYL GLUCOSIDE (UNII: 6JVVW35JOOJ)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

CETYL ALCOHOL (UNII: 936JST6JCN)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	
BROWN IRON OXIDE (UNII: 1N032N7MFO)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82800-010-01	1 in 1 PACKAGE	09/21/2023	
1		50 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	part352	09/21/2023	

Labeler - The Center Brands, LLC (076228814)

Revised: 9/2023

The Center Brands, LLC