

PROTEKT SPF-50 SHEER MINERAL SUNSCREEN- zinc oxide cream
Protekt Products, Inc.

PROTEKT SPF-50 Sheer Mineral Sunscreen

Drug Facts

Active Ingredients

Zinc Oxide 18.00%

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 ask a doctor if

- rash or irritation develops and lasts.

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.

- Reapply:
- 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: **Sun Protection Measures.**
- 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:

*Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), *Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, *Carthamus Tinctorius (Safflower) Oil, Citric Acid, Cocos Nucifera (Coconut) Oil, Decyl Glucoside, Glycerin, Dodecane, Glyceryl Caprylate, Glyceryl Stearate Citrate, Glyceryl Undecylenate, *Helianthus Annuus (Sunflower) Oil, Hydrogenated Methyl Abietate, Isododecane, Polyhydroxystearic Acid, *Punica Granatum (Pomegranate) Extract, Stearic Acid, Tetrasodium Glutamate Diacetate, *Theobroma Cacao (Cocoa) Butter, Tocopherol, Tridecyl Salicylate, Trimethylsiloxysilicate, Xanthan Gum

(*Certified Organic Ingredient)

Package Labeling:

Drug Facts	
Active Ingredients	Purpose
Zinc Oxide 18.00%	Sunscreen
Uses:	
<ul style="list-style-type: none"> Helps prevent sunburn. Higher SPF gives more sunburn protection. reapplies 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 ask a doctor if rash or irritation develops and lasts.	
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:	
<ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure and as needed. Children under 6 months of age: ask a doctor. Reapply: <ul style="list-style-type: none"> after 80 minutes of swimming or sweating immediately after towel drying 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 the risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> 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: Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), *Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, *Carthamus Tinctorius (Safflower) Oil, Citric Acid, Cocos Nucifera (Coconut) Oil, Decyl Glucoside, Glycerin, Dodecane, Glyceryl Caprylate, Glyceryl Stearate Citrate, Glyceryl Undecylenate, *Helianthus Annuus (Sunflower) Oil, Hydrogenated Methyl Abietate, Isododecane, Polyhydroxystearic Acid, *Punica Granatum (Pomegranate) Extract, Stearic Acid, Tetrasodium Glutamate Diacetate, *Theobroma Cacao (Cocoa) Butter, Tocopherol, Tridecyl Salicylate, Trimethylsiloxysilicate, Xanthan Gum (*Certified Organic Ingredient)	
MANUFACTURED FOR: PROTEKT PRODUCTS INC. 1676 MAIN ST. SAN DIEGO, CA 92113 PROTEKT.COM MADE IN THE USA	

PROTEKT SPF-50 SHEER MINERAL SUNSCREEN
zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82912-323
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	180 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0K00R)	
GREEN TEA LEAF (UNII: WZZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SAFFLOWER (UNII: 4VBL71TY4Y)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
DODECANE (UNII: 11A386X1QH)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
HYDROGENATED METHYL ABIETATE (UNII: A23O709X8O)	
ISODODECANE (UNII: A8289P68Y2)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
COCOA (UNII: D9108TZ9KG)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82912-323-00	170 g in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/01/2022	

