

DERMAKA BROAD SPECTRUM SPF-42 SUNSCREEN- titanium dioxide, zinc oxide cream
DERMAKA SKIN PRODUCTS

DERMAKA Broad Spectrum SPF-42 Sunscreen

DRUG FACTS

Active Ingredients

Titanium dioxide 6.00% Zinc Oxide 7.70%

Purpose

Sunscreen

USES:

- Helps prevent sunburn.
- higher SPF gives more sunburn protection
- If used as directed with other sun protection measures (see), decreases the risk of skin cancer and early skin aging caused by the sun **Directions**

WARNINGS:

not intended for ingestion. **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.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure.
- 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), Bromelain, Butyloctyl Salicylate, Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Caprylyl/Capryl Glucoside, Capryloyl Glycerin/Sebacic Acid Copolymer, Cetearyl Alcohol, Chamomilla Recututa (Chamomile) Extract, Citrullus Lanatus (Watermelon) Extarct, Cocos Nucifera (Coconut) Oil, Dodecane, Glycerin, Glyceryl Caprylate, Glyceryl Stearate, Glyceryl Undecylenate, Glycyrrhiza Glabra (Licorice) Extarct, Hawthorn Extract, Helianthus Annuus (Sunflower) Oil, Hydroxyethylcellulose, Iron Oxides (Black, Red, White, Yellow), Polyhydroxystearic Acid, Sambucus Nigra (Elderberry) Extarct, Sodium Polyacrylate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Zemea (Corn) Propanediol.

Questions?

(772) 266-3376

Package Labeling:

dermaka

**BROAD SPECTRUM
SPF 42 SUNSCREEN**
80 MIN WATER RESISTANT
TINTED - 3.4 FL OZ (100mL)



DRUG FACTS

Active Ingredients	Purpose
Titanium dioxide 6.00 %	Sunscreen
Zinc Oxide 7.70 %	Sunscreen

USES:

- Helps prevent sunburn.
- higher SPF gives more sunburn protection
- 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 not intended for ingestion.

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.

DIRECTIONS:

- Apply liberally 15 minutes before sun exposure.
- 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
- **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:
 - 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), Bromelain, Butyloctyl Salicylate, Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Caprylyl/Capryl Glucoside, Capryloyl Glycerin/Sebacic Acid Copolymer, Cetearyl Alcohol, Chamomilla Recutita (Chamomile) Extract, Citrullus Lanatus (Watermelon) Extract, Cocos Nucifera (Coconut) Oil, Dodecane, Glycerin, Glyceryl Caprylate, Glyceryl Stearate, Glyceryl Undecylenate, Glycyrrhiza Glabra (Licorice) Extract, Hawthorn Extract, Helianthus Annuus (Sunflower) Oil, Hydroxyethylcellulose, Iron Oxides (Black, Red, White, Yellow), Polyhydroxystearic Acid, Sambucus Nigra (Elderberry) Extract, Sodium Polyacrylate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Zemea (Corn) Propanediol.*

Questions?
(772) 266-3376

Dermaka Skin Products, Inc.

7805 SW Ellipse Way # A-3

Stuart, FL 34997

772.266.3376

info@dermaka.com

www.dermaka.com

3.0 mm

DERMAKA BROAD SPECTRUM SPF-42 SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:82240-223

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	60 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	77 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BROMELAINS (UNII: U182GP2CF3)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHAMOMILE (UNII: FGL3685T2X)	
WATERMELON (UNII: 231473QB6R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
DODECANE (UNII: 11A386X1QH)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
LICORICE (UNII: 61ZBX54883)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CORN (UNII: 0N8672707O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82240-223-00	100 mL in 1 TUBE; Type 0: Not a Combination Product	09/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	09/21/2021	

