

FRE PROTECT BODY ULTRA-LIGHT GEL CREAM SPF 50- zinc oxide jelly
Peer Pharm Ltd.

FRE PROTECT BODY Ultra-Light Gel Cream SPF 50

Active ingredients

Zinc Oxide 24%

Purpose

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.
- 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

Keep out of reach of children

Inactive Ingredients

Water, Coco-Caprylate/Caprates, Dicaprylyl Ether, Glycerin, Propanediol, Polyglyceryl-6 Stearate, Silica, Polyhydroxystearic Acid, Vitis Vinifera (Grape) Seed Oil, Rosa Canina Fruit Extract, Niacinamide, Butyrospermum Parkii (Shea) Butter, Simmondsia Chinensis (Jojoba) Seed Oil, Triethoxycaprylylsilane, Cetyl Alcohol, Xanthan Gum, Caprylyl Glycol, Glyceryl Stearate, Argania Spinosa Kernel (Argan) Oil, Panthenol, Ascorbyl Tetraisopalmitate, Lecithin, Sclerotium Gum, Pullulan, Polyglyceryl-6 Behenate, Caprylhydroxamic Acid, Tocopherol, Pongamia

Pinnata Seed Extract, Pongamol, Argania Spinosa Leaf Extract, Argania Spinosa Callus Culture Extract, Isomalt, Cananga Odorata Flower (Ylang-Ylang) Oil.

Directions

- Apply liberally 15 minutes before sun exposure.
- 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 this risk, regularly use a sunscreen with a broad-spectrum SPF value of 15 or higher and other sun protection measures.
- Limit time in the sun, especially from 10 a.m.-2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.
- For children under 6 months of age: Ask a doctor.





Other information

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

- Do not use if the seal is broken.

Questions & Comments?

Call toll free 1-888-589-6243

<p>Drug Facts</p> <p>Active ingredients Purpose Zinc Oxide 24%.....Sunscreen</p> <p>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.</p> <p>Warnings • For external use only. • Do not use on damaged or broken skin. • When using this product, keep out of eyes. <u>Rinse with water to remove.</u> • 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.</p> <p>Directions • Apply liberally 15 minutes before sun exposure. • 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 this risk, regularly use a sunscreen with a broad-spectrum SPF value of 15 or higher and other sun protection measures. • Limit time in the sun, especially from 10 a.m.-2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses. • For children under 6 months of age: Ask a doctor.</p> <p>Other information • Protect this product in this container from excessive heat and direct sun. • Do not use if the seal is broken.</p> <p>Inactive Ingredients Water, Coco-Caprylate/Caprate, Dicaprylyl Ether, Glycerin, Propanediol, Polyglyceryl-6 Stearate, Silica, Polyhydroxystearic Acid, Vitis Vinifera (Grape) Seed Oil, Rosa Canina Fruit Extract, Niacinamide, Butyrospermum Parkii (Shea) Butter, Simmondsia Chinensis (Jojoba) Seed Oil, Triethoxycaprylylsilane, Cetyl Alcohol, Xanthan Gum, Caprylyl Glycol, Glyceryl Stearate, Argania Spinosa Kernel (Argan) Oil, Panthenol, Ascorbyl Tetraisopalmitate, Lecithin, Sclerotium Gum, Pullulan, Polyglyceryl-6 Behenate, Caprylhydroxamic Acid, Tocopherol, Pongamia Pinnata Seed Extract, Pongamol, Argania Spinosa Leaf Extract, Argania Spinosa Callus Culture Extract, Isomalt, Cananga Odorata Flower (Ylang-Ylang) Oil.</p> <p>Questions & Comments? Call toll free 1-888-589-6243</p>	 <p>100% Mineral Sunscreen (Non-Nano Zinc Oxide)</p>	<h1>FRE</h1>	
 <p>Water Resistant (80 Min.)</p>	<p>PROTECT BODY 100% Mineral Sunscreen</p>	<p>Broad Spectrum SPF 50 Water Resistant (80 Min.) Ultra-Light Gel Cream </p>	<p>With Argania Active Complex™ Vitamin C & Niacinamide</p>
 <p>Cosmetrade S.L. Avenida Sudáfrica, 10, 1408 (Cádiz) Spain Cosmetrade UK Ltd. 126 Wigmore Street, London W1U 3RZ UK DISTRIBUTED BY/ DISTRIBUÉ PAR FRE Skincare, 1013 Centre Road, Suite 403-B, Wilmington, Delaware 19805. Made in Israel Fabriqué en Israël freskincare.com</p>	<p>3.38 fl. oz. (100mL) e</p>		

FRE PROTECT BODY ULTRA-LIGHT GEL CREAM SPF 50

zinc oxide jelly

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69435-1412
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPANEDIOL (UNII: 5965N8W85T)	
POLYGLYCERYL-6 STEARATE (UNII: ETY9Q81E2T)	
SILICA (UNII: ETJ7Z6XBU4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
NIACINAMIDE (UNII: 25X51I8RD4)	
SHEA BUTTER (UNII: K49155WL9Y)	
JOJOBA OIL (UNII: 724GKU717M)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
PANTHENOL (UNII: WW9CM0067Z)	
ARGAN OIL (UNII: 4V59G5UW9X)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SCLEROTIUM GUM (UNII: 2X51AD1X3T)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
POLYGLYCERYL-6 BEHENATE (UNII: 4T2L7QI313)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PONGAMIA PINNATA SEED (UNII: C2BRV53B1V)	
PONGAMOL (UNII: 8Y19QCY6I4)	
ARGANIA SPINOSA LEAF (UNII: 51XV5WTF7E)	
ISOMALT (UNII: S870P55O2W)	
YLANG-YLANG OIL (UNII: 8YOY78GNNX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1412-1	1 in 1 CARTON	01/14/2025	
1		100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/14/2025	

