

**FRE PROTECT ME LIGHTWEIGHT DAILY MOISTURIZER SPF 50- zinc
oxide cream
Peer Pharm Ltd.**

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 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, call a Poison Control Center or get medical help right away.

Directions

- Shake well before use
- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 40 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 including:

- limit time in the sun, especially from 10a.m. to 2p.m.
- Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: ask a doctor

Other information

Protect the product in this container from excessive heat and direct sun. Do not use if the seal is broken.

Inactive Ingredients

Water (Aqua), Coco-Caprylate, Glyceryl Oleate Citrate, Stearyl/Octyldodecyl Citrate Crosspolymer, Tocopherol, Argania Spinosa Kernel Oil, Polyhydroxystearic Acid, Panthenol, Triethoxycaprylylsilane, Lauryl Glucoside, Polyglyceryl-6 Laurate, Propanediol, Xanthan Gum, Myristyl Glucoside, Caprylic/Capric Triglyceride, Isomalt, Glycerin, Caprylyl Glycol, Lauroyl Lysine, Sodium Phytate, Argania Spinosa Leaf Extract, Ethylhexylglycerin, Caprylhydroxamic Acid, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Cymbopogon Flexuosus Oil, Lavandula Angustifolia (Lavender) Oil, Carnosine, Argania Spinosa Callus Culture Extract, Lecithin.

Questions or Comments

Call 951-297-7976 or visit www.kcare.co.il

Product label

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Other information


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Questions & Comments?


Call toll free 1-888-589-6243



100% Mineral
Sunscreen
(Non Nano Zinc Oxide)




Water Resistant



Won't Sting Eyes

FRÉ



PROTECT ME 50
Lightweight Daily Moisturizer


MINERAL SUNSCREEN
Broad Spectrum SPF 50
Water Resistant (40 Minutes)

With Argania Active Complex™




1.69 FL. OZ. (50mL) e

Cosmetradora S.L. Avenida Sudáfrica, 110. T1408 (Cádiz) Spain
Cosmetradora UK Ltd. 126 Wigmore Street, London W1U 3RZ UK

DISTRIBUTED BY/ DISTRIBUÉ PAR
FRÉ Skincare, 1013 Centre Road, Suite 403-B, Wilmington, Delaware 19805. freskincare.com



Fabriqué en Israël
Made in Israel

FRE PROTECT ME LIGHTWEIGHT DAILY MOISTURIZER SPF 50

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69435-1404
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 (UNII: 4828G836N6)
GLYCERYL MONOOLEATE CITRATE (UNII: NLE5KIG74K)
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK)
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)
XANTHAN GUM (UNII: TTV12P4NEE)
PANTHENOL (UNII: WW9CM0O67Z)
PROPANEDIOL (UNII: 5965N8W85T)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
ISOMALT (UNII: S870P55O2W)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
GLYCERIN (UNII: PDC6A3C0OX)
MYRISTYL GLUCOSIDE (UNII: 6AK28695LF)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
PHYTATE SODIUM (UNII: 88496G1ERL)
LAUROYL LYSINE (UNII: 113171Q70B)
ARGANIA SPINOSA LEAF (UNII: 51XV5WTF7E)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
TOCOPHEROL (UNII: R0ZB2556P8)
BERGAMOT OIL (UNII: 39W1PKE3JI)
EAST INDIAN LEMONGRASS OIL (UNII: UP0M8M3VZW)
LAVENDER OIL (UNII: ZBP1YXW0H8)
CARNOSINE (UNII: 8HO6PVN24W)
ARGAN OIL (UNII: 4V59G5UW9X)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1404-1	1 in 1 CARTON	02/15/2023	
1		50 mL 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 not final	part352	02/15/2023	

Labeler - Peer Pharm Ltd. (514678390)

Registrant - Peer Pharm Ltd. (514678390)

Establishment

Name	Address	ID/FEI	Business Operations
Peer Pharm Ltd.		514678390	manufacture(69435-1404)

Revised: 2/2023

Peer Pharm Ltd.