

FRE GLOW ME LIGHTWEIGHT TINTED MOISTURIZER MEDIUM DEEP- 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 19.2%

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 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 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, Titanium Dioxide, Iron Oxide Yellow (CI 77492), Lauryl Glucoside, Xanthan Gum, Panthenol, Argania Spinosa Kernel Oil, Polyglyceryl-6 Laurate, Propanediol, Polyhydroxystearic Acid, Triethoxycaprylylsilane, Isomalt, Caprylic/Capric Triglyceride, Glycerin, Myristyl Glucoside, Caprylyl Glycol, Sodium Phytate, Lauroyl Lysine, Argania Spinosa Leaf Extract, Caprylhydroxamic Acid, Tocopherol, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Cymbopogon Flexuosus Oil, Lavandula Angustifolia (Lavender) Oil, Carnosine, Argania Spinosa Callus Culture Extract, Lecithin, Iron Oxide Red (CI 77491), Iron Oxide Black (CI 77499).

Questions or Comments

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

Product label

<p>Drug Facts</p> <p>Active Ingredients Purpose Zinc Oxide 19.2%.....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. 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.</p> <p>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. • 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 the product in this container from excessive heat and direct sun. Do not use if the seal is broken.</p> <p>Inactive Ingredients Water (Aqua), Coco-Caprylate, Glyceryl Oleate Citrate, Stearyl Octyldodecyl Citrate Copolymer, Titanium Dioxide, Iron Oxide Yellow (CI 77492), Lauryl Glucoside, Xanthan Gum, Panthenol, Argania Spinosa Kernel Oil, Polyglyceryl-6 Laurate, Propenediol, Polyhydroxyesteric Acid, Triethoxypropylsilane, Isomethyl Caprylo/Capric Triglyceride, Glycerin, Myristyl Glucoside, Caprylyl Glycol, Sodium Phytate, Lauryl Lysine, Argania Spinosa Leaf Extract, Caprylylhydroamic Acid, Tocopherol, Citrus Aurantium Bergamia (Bergamot) Fruit Oil, Cymbopogon Flexuosus Oil, Lavandula Angustifolia (Lavender) Oil, Camosine, Argania Spinosa Callus Culture Extract, Lecithin, Iron Oxide Red (CI 77491), Iron Oxide Black (CI 77499).</p> <p>Questions & Comments? Call toll free 1-888-589-8243</p>	<p style="text-align: center;"></p> <p style="text-align: center;">100% Mineral Sunscreen (Non Nano Zinc Oxide)</p> <p style="text-align: center;"></p> <p style="text-align: center;">Water Resistant</p> <p style="text-align: center;"></p> <p style="text-align: center;">Won't Sting Eyes</p>	<p style="text-align: center; font-size: 2em; font-weight: bold;">FRÉ</p> <p style="text-align: center;"></p> <p style="text-align: center; font-weight: bold;">GLOW ME +</p> <p style="text-align: center;">Lightweight Tinted Moisturizer</p> <p style="text-align: center; font-weight: bold;">MINERAL SUNSCREEN</p> <p style="text-align: center;">Broad Spectrum SPF 30 Water Resistant (40 Minutes)</p> <p style="text-align: center;">Medium - Deep</p> <p style="text-align: center;">With Argania Active Complex™</p> <p style="text-align: center;">1.69 FL. OZ. (50mL) e</p>	
<p>Cosmetrade S.L. Avenida Sudfrica, 110, 1140B (Cádiz) Spain Cosmetrade UK Ltd. 126 Wigmore Street, London W1U 3RZ UK</p> <p>DISTRIBUTED BY/ DISTRIBUÉ PAR FRÉ Skincare, 1015 Centre Road, Suite 403-B, Wilmington, Delaware 19805. freskinca.com</p> <p>    Fabriqué en Israël Made in Israel</p>	<p style="text-align: center;">Non-Comedogenic Hypoallergenic No Synthetic Fragrance Vegan Reef-Safe</p>		

FRE GLOW ME LIGHTWEIGHT TINTED MOISTURIZER MEDIUM DEEP

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69435-1402
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19.2 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: WW9CM0067Z)
PROPANEDIOL (UNII: 5965N8W85T)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
ISOMALT (UNII: S870P5502W)
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)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1402-1	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(69435-1402)

Revised: 2/2023

Peer Pharm Ltd.