

**FRE GLOW ME SPF 50 LIGHTWEIGHT TINTED MOISTURIZER MEDIUM DEEP-zinc oxide cream**  
**Peer Pharm Ltd**

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**FRE GLOW ME SPF 50 Lightweight Tinted Moisturizer Medium-Deep**

**Drug Facts**

**Active ingredients**

Zinc Oxide 24.0%

**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 or contact a Poison Control Center 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.
- 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 the product in this container from excessive heat and direct sun. Do not use if the seal is broken.

### **Inactive Ingredients**

Water, 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, Caprylhydroxamic Acid, Cymbopogon Flexuosus Oil, Lavandula Angustifolia (Lavender) Oil, Carnosine, Argania Spinosa Callus Culture Extract, Lecithin, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499).

### **Questions and Comments**

Call toll free 1-888-589-6243

<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> <span style="float: right;"><b>Purpose</b></span> Zinc Oxide 24.0% <span style="float: right;">Sunscreen</span></p> <p><b>Uses</b> • Helps prevent sunburn. • If used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun.</p> <p><b>Warnings</b> • <b>For external use only.</b> • <b>Do not use</b> on damaged or broken skin. • <b>When using this product</b>, keep out of eyes. Rinse with water to remove. • <b>Stop use and ask a doctor</b> if rash occurs. • <b>Keep out of reach of children.</b> • If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> • 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. • <b>Sun protection measures:</b> 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><b>Other information</b> Protect the product in this container from excessive heat and direct sun. Do not use if the seal is broken.</p> <p><b>Inactive Ingredients</b> Water, Coco-Caprylate, Glyceryl Stearate Citrate, Stearyl Octyldodecyl Citrate Crosspolymer, Tocopherol, Argania Spinosa Kernel Oil, Polyhydroxyesteric Acid, Panthenol, Triethoxycaprylylsilane, Lauryl Glucoside, Polyglyceryl-6 Laurate, Propanediol, Xanthan Gum, Myristyl Glucoside, Capryloyl Capric Triglyceride, Isomalt, Glycerin, Caprylyl Glycol, Lauryl Lysine, Sodium Phytate, Argania Spinosa Leaf Extract, Caprylhydroxamic Acid, Cymbopogon flexuosus Oil, Lavandula Angustifolia (Lavender) Oil, Camosine, Argania Spinosa Cellus Culture Extract, Lecithin, Iron Oxides (CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499).</p> <p><b>Questions &amp; Comments?</b> Call toll free 1-888-689-6243</p> <p><small>Cosmetrade S.L., Avenida Sudáfrica, 110, 11408 (Cádiz) Spain Cosmetrade UK Ltd, 126 Wigmore Street, London W1U 3RZ UK</small></p> <p><b>DISTRIBUTED BY/ DISTRIBUÉ PAR</b> FRE Skincare, 1013 Centre Road, Suite 403-B, Wilmington, Delaware 19805, <a href="http://freskincare.com">freskincare.com</a></p> <p>Fabriqué en Israël Made in Israel</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 + 50</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 50 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 style="text-align: center;">Non-Comedogenic Hypoallergenic No Synthetic Fragrance Vegan</p>		<p style="text-align: center; border: 1px solid black; padding: 5px;">7290020091390</p>	

## FRE GLOW ME SPF 50 LIGHTWEIGHT TINTED MOISTURIZER MEDIUM DEEP

zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69435-1408
<b>Route of Administration</b>	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
GLYCERYL MONOOLEATE CITRATE (UNII: NLE5KIG74K)	
EAST INDIAN LEMONGRASS OIL (UNII: UP0M8M3VZW)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ARGANIA SPINOSA LEAF (UNII: 51XV5WTF7E)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
PANTHENOL (UNII: WW9CM0O67Z)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
STEARYL/OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: PN88NW0KPK)	
TOCOPHEROL (UNII: ROZB2556P8)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-6 LAURATE (UNII: Q48X4BL3TV)	
MYRISTYL GLUCOSIDE (UNII: 6AK28695LF)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
ARGAN OIL (UNII: 4V59G5UW9X)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPANEDIOL (UNII: 5965N8W85T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
CARNOSINE (UNII: 8HO6PVN24W)	
ARGANIA SPINOSA WHOLE (UNII: 83K6O4FR76)	
WATER (UNII: 059QF0K00R)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISOMALT (UNII: S870P55O2W)	
LAUROYL LYSINE (UNII: 113171Q70B)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1408-1	1 in 1 CARTON	07/15/2024	
1		50 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	07/15/2024	

**Labeler** - Peer Pharm Ltd (514678390)

**Registrant** - Peer Pharm Ltd (514678390)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Peer Pharm LTD		514678390	manufacture(69435-1408)

Revised: 7/2024

Peer Pharm Ltd