FRE GLOW ME LIGHTWEIGHT TINTED MOISTURIZER LIGHT MEDIUM- 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 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 10 am to 2 p.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.

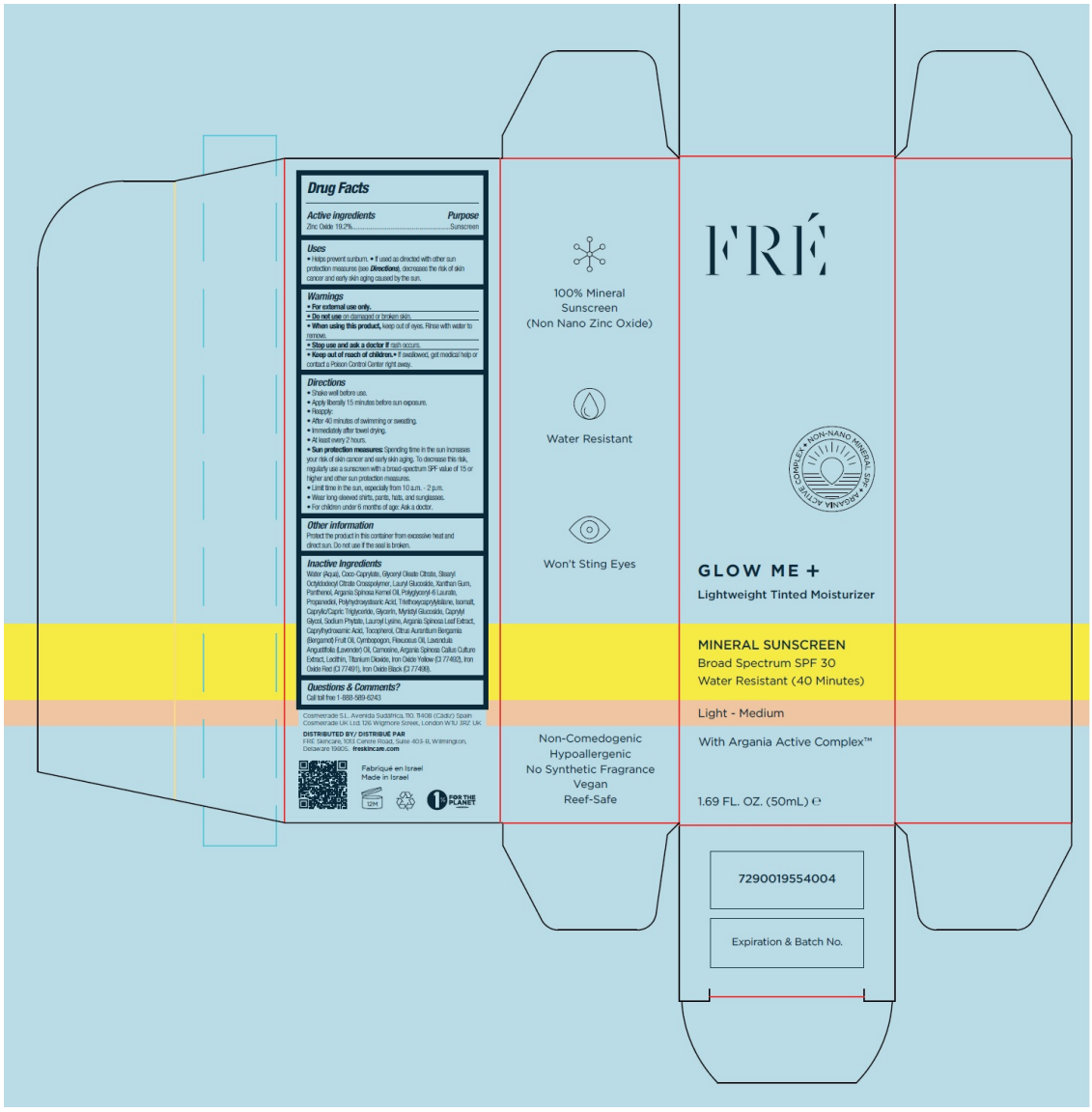
Inactive Ingredients

Water (Aqua), Coco-Caprylate, Glyceryl Oleate Citrate, Stearyl Octyldodecyl Citrate Crosspolymer, 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, Titanium Dioxide, Iron Oxide Yellow (CI 77492), 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



FRE GLOW ME LIGHTWEIGHT TINTED MOISTURIZER LIGHT MEDIUM

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69435-1401
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: WV9CM0O67Z)	
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)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1401-1	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(69435-1401)

Revised: 2/2023

Peer Pharm Ltd.