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 AurantiumBergamia (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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Instruction Ingredients Won't Sting Eyes PROTECT ME 50 Water (Auali, Cao-Caprilate, Byperf) (Date Consequence, Toospherd, Agains Sphose Lead, Byperf) (Date Consequence, C	contact a Poison Control Center right sway. Directions • Shole well before use. • Apply liberally 15 minutes before sun exposure. • Reappi: • Mar 40 minutes of swimming or sweeting. • Immediately after tweet of typing. • At least every 2 hours: • Sun protections measures: Spending time in the sun increases your risk of skin cancer and setly skin aging. To decrease this risk, regularly use a sunscream with a brack-spectrum SFF value of 15 or higher and other sun protection measures: • Limit time in the sun, expecially time 10 am 2 pm. • Wear long-sleeved shirts, pants, hats, and sunglasses. • For children under 6 months of age. Aek a doctor. Different function the product in this container from excessive heat and	Water Resistant	A GANNAR CONTRACTOR CO	
Laryol Lysins, Sodium Phytote, Argania Spinosa Leaf Datart, Ettylifex/glosein, Capylhydroxamic Acid, Chrus Aurantium Bergamig (Bergamot Finill OL, Omboogon Fiew.cosus OL, Spinosa Callus Cuture Extract, Lecthin. Destamic Adult Suture Extract, Lecthin. Destamic Adult Suture Extract, Lecthin. Destamic Sector Extract, Sector Extract, Lecthin. Non-Comedogenic Hypoallergenic No Synthetic Fragrance Vegan	Inactive Ingredients Water (Aqua), Coco-Capylate, Glyceryl Oleste Citrate, Steryl/Octyldodecyl Citrate Crosspolymer, Tocopherol, Argania Spinosa Kemel OII, Polyhydroxystearic Acid, Pantherol, Triethoxycapryl/silane, Lauryl Glucoside, Polyglyceryl-6 Laurate, Propendiol, Xarthan Gum, Myristy Glucoside,	Won't Sting Eyes		
Cosmerrado SL. Avenida Sudatrica, 10. 1408 (Cadir) Spain Cosmerrado LK Ltd. 106 Wigmone Street, London W1U 382 LK DistributEd BX/D DistributE 9AP FRE Skincare, 1013 Centre Road, Suite 403-B, Wilmington, Detaware 1805 testificare.com Pabriqué en Israel Made in Israel Wegan	Lauroyi Lysine, Sodium Phytate, Argania Spinosa Leaf Editact, Ethylhesylgiverin, Capyrihydroxamic Acid, Chrus Aurantium Bergamis (Berginant) Finit (OL Cymbopogon Feuxosus Oli, Lsvandula Angustifolia (Lavender) Oli, Carnosine, Argania Spinosa Callus Culture Extract, Leothin. Questions & Comments?		Broad Spectrum SPF 50	
	Cosmetrade S.L. Avenida Sudálhica, 110. 11408 (Cádiz) Spain Cosmetrade UK. Lid. 126 Wigmore Street, London WTU 372. UK DISTRIBUTED BY/ DISTRIBUÉ PAR FRÉ Skincark, 012 Carrer Road, Suite 403-B, Wilmington, Delaware 19805. freeklincare.com Fabriqué en Israel	Hypoallergenic No Synthetic Fragrance Vegan		

FRE PROTECT ME LIGHTWEIGHT DAILY MOISTURIZER SPF 50

zinc oxide cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code	e (Source)	NDC:6	59435-1404
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Active mgreatent/Active	indicty				
Ingredient Name Basis of Strength				gth	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 2			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: WV9CM0067Z)	
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)	
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 I	nformation				
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.