

**MILD CARE SUNCREAM- zinc oxide cream
HUMEX,INC.**

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 ingredient Purpose

Zinc Oxide(15.445) Sunscreen

Uses

Helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

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 (1-800-222-1222) right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating
- Children under 6 months of age: ask a doctor

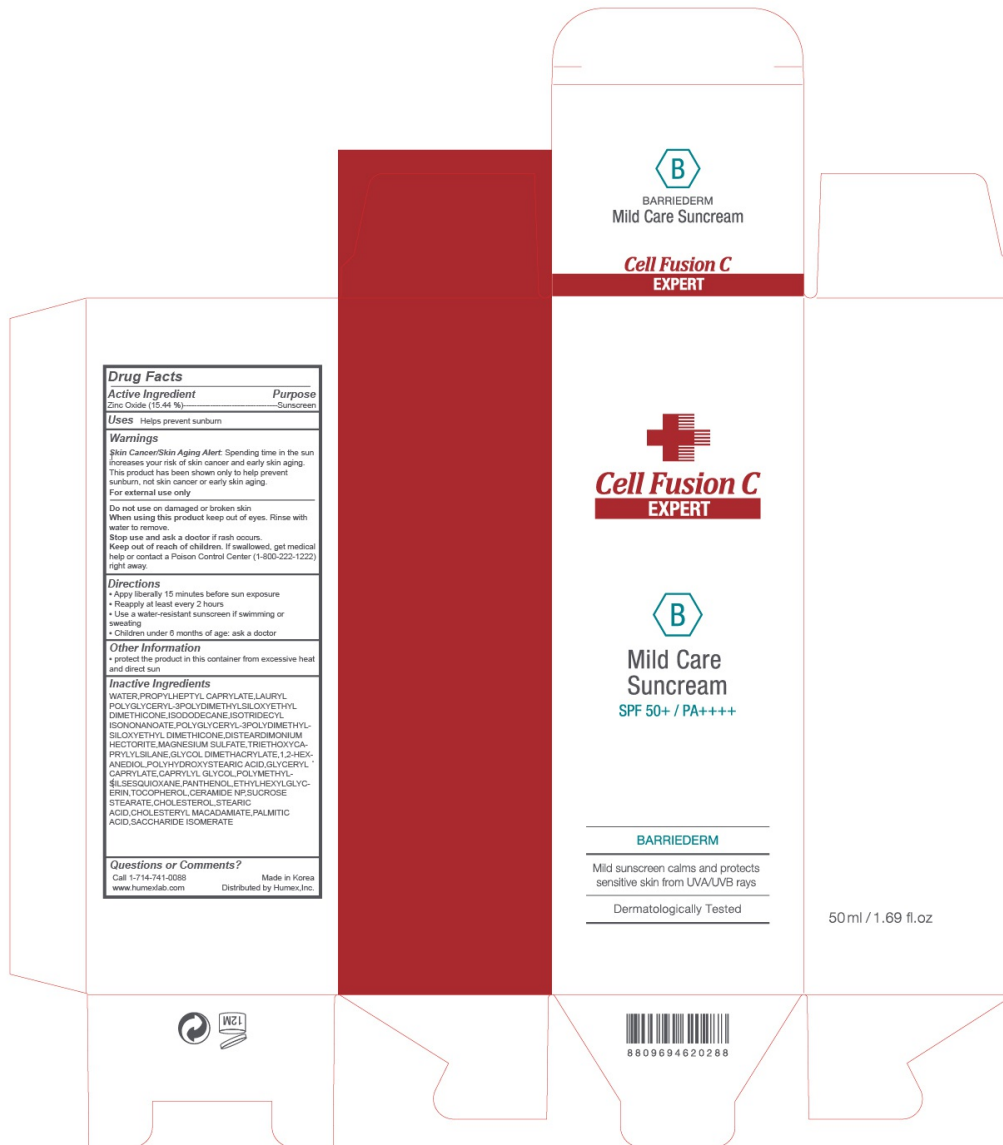
Other Information

- protect the product in this container from excessive heat and direct sun

Inactive Ingredients

WATER, PROPYLHEPTYL CAPRYLATE, LAURYL POLYGLYCERYL-3POLYDIMETHYLSILOXYETHYL DIMETHICONE, ISODODECANE, ISOTRIDECYL ISONONANOATE, POLYGLYCERYL-3POLYDIMETHYLSILOXYETHYL DIMETHICONE, DISTEARDIMONIUM HECTORITE, MAGNESIUM SULFATE, TRIETHOXYCAPRYLYLSILANE, GLYCOL DIMETHACRYLATE, 1,2-HEXANEDIOL, POLYHYDROXYSTEARIC ACID, GLYCERYL CAPRYLATE, CAPRYLYL GLYCOL, POLYMETHYLSILSESQUIOXANE, PANTHENOL, ETHYLHEXYLGLYCERIN, TOCOPHEROL, CERAMIDE NP, SUCROSE STEARATE, CHOLESTEROL, STEARIC ACID, CHOLESTERYL MACADAMATE, PALMITIC ACID, SACCHARIDE ISOMERATE

Package display panel



MILD CARE SUNCREAM

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76344-8006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15.44 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ISOTRIDECYL ISONONANOATE (UNII: WEF51750MT)	2 g in 100 mL
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	0.8 g in 100 mL
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	0.63 g in 100 mL
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	0.1 g in 100 mL
PANTHENOL (UNII: WW9CM0067Z)	0.07 g in 100 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.04 g in 100 mL
TOCOPHEROL (UNII: R0ZB2556P8)	0.01 g in 100 mL
CHOLESTERYL MACADAMIATE (UNII: DFP79OD7KP)	0.01 g in 100 mL
PALMITIC ACID (UNII: 2V16EO95H1)	0.01 g in 100 mL
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	0.01 g in 100 mL
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	2.39 g in 100 mL
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	0.1 g in 100 mL
SUCROSE STEARATE (UNII: 274KW0050M)	0.01 h in 100 mL
CHOLESTEROL (UNII: 97C5T2UQ7J)	0.01 g in 100 mL
STEARIC ACID (UNII: 4ELV7Z65AP)	0.01 g in 100 mL
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	12.49 g in 100 mL
ISODODECANE (UNII: A8289P68Y2)	2 g in 100 mL
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	0.8 g in 100 mL
GLYCOL DIMETHACRYLATE (UNII: 7BK5G69305)	0.6 g in 100 mL
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	0.3 g in 100 mL
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	0.16 g in 100 mL
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	0.1 g in 100 mL
CERAMIDE NP (UNII: 4370DF050B)	0.01 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76344-8006-2	1 in 1 BOX	01/01/2021	
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 final	part352	01/01/2021	

Labeler - HUMEX,INC. (017945311)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea		689512611	manufacture(76344-8006)

Revised: 1/2023

HUMEX,INC.