# CALMPOSE REPAIRY LIGHT DERMA SUN- zinc oxide cream Ecoment

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.

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#### ACTIVE INGREDIENT

Zinc Oxide 23%

#### INACTIVE INGREDIENTS

Water, Dicaprylyl Carbonate, Caprylic/Capric Triglyceride, CentellaAsiatica Extract, Polyglyceryl-3 Diisostearate, Polyglyceryl-2 Dipolyhydroxystearate, Silica, SimmondsiaChinensis (Jojoba) Seed Oil, Pentylene Glycol, \*Beeswax, Sodium Chloride, Dicaprylyl Ether, Glycerin, Betaine, Sodium Levulinate, GlycerylCaprylate, Sodium Anisate, Madecassoside, Squalane, Helianthus Annuus (Sunflower) Seed Oil, Asiaticoside, Propanediol, ButyrospermumParkii (Shea) Butter, TriticumVulgare (Wheat) Germ Oil, Sodium Hyaluronate, Hydrolyzed Hyaluronic Acid, Hyaluronic Acid, Ceramide NP, Phytosphingosine, Polyglutamic Acid, ChamomillaRecutita (Matricaria) Flower Extract, RobiniaPseudoacacia Flower Extract, Prunus Yedoensis Flower Extract, Rosa Multiflora Flower Extract, Rhamnose, Glucose, Glucuronic Acid, PyrusCommunis (Pear) Fruit Extract, Rosa Damascena Flower Water, Iris Florentina Root Extract, CucumisMelo (Melon) Fruit Extract, Hedera Helix (Ivy) Leaf/Stem Extract, Tocopherol

#### **PURPOSE**

Sunscreen

#### WARNINGS

For external use only Avoid contact with eyes. Discontinue use if signs of irritation or rashes appear. Replace the cap after use. Keep out of reach of children

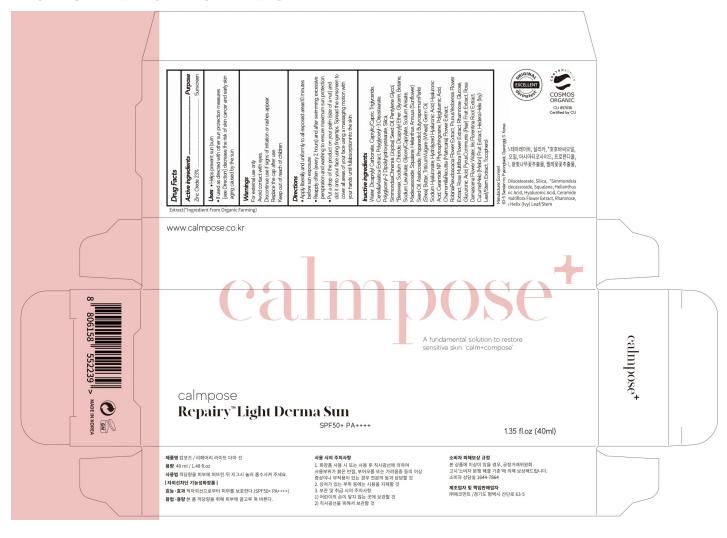
#### Uses

- Helps prevent sun burn
- If used as directed with other sun protection measures [see Direction] decrease the risk of skin cancer and early skin aging caused by the sun

#### **Directions**

- Apply liberally and uniformly to all exposed areas 10 minutes before sun exposure.
- Reapply often (every 2 hours) and after swimming, excessive perspiration and washing to ensure maximum sun protection.
- Put a drop of the product on your palm (size of a nut) and dot it onto your face using fingertips. Spread the sunscreen to cover all areas of your face using a massaging motion with your hands until full absorption into the skin.

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



### CALMPOSE REPAIRY LIGHT DERMA SUN

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78958-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
2	Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	9.2 g in 40 mL

Inactive Ingredients				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)				
Dicaprylyl Carbonate (UNII: 609 A3V1SUA)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:78958-010- 02	1 in 1 CARTON	10/01/2020	
	1 NDC:78958-010- 01	40 mL in 1 CONTAINER; 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	10/01/2020		

## **Labeler** - Ecoment (688485136)

## Registrant - Ecoment (688485136)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ecoment		688485136	manufacture(78958-010)	

Revised: 10/2020 Ecoment