# LASER SUNSCREEN 100- octisalate, octinoxate, zinc oxide, titanium dioxide cream CMS LAB 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.

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### Laser Sunscreen 100

### Active ingredients

Octinoxate (7.5%) Octisalate (5%) Zinc Oxide (4.8%) Titanium Dioxide (2.49%)

### Purpose

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 when skin is red, inflamed, irritated, or painful

When using this product

- do not apply on other parts of the body
- do not use on damaged or broken skin
- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water
- do not apply directly to wound or open cut

Stop use and ask a doctor if

- Rash or irritation on skin develops and lasts

### 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 the adequate amount onto the entire face at the last stage of your skin care routine. Re-apply frequently and generously to maintain protection. the palm of the hands and pat lightly with the fingertips.

- 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

### **Inactive ingredients**

WATER, CYCLOPENTASILOXANE, BUTYLENE GLYCOL, DIPROPYLENE GLYCOL, DICAPRYLYL CARBONATE, PEG-10 DIMETHICONE, LAURYL PEG-8 DIMETHICONE, DIMETHICONE, DISTEARDIMONIUM HECTORITE, MAGNESIUM SULFATE, PHENYL TRIMETHICONE, METHYL METHACRYLATE CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, PHENOXYETHANOL, ALUMINUM HYDROXIDE, ALUMINUM STEARATE, METHICONE, POLYGLYCERYL-6 POLYRICINOLEATE, CAPRYLYL GLYCOL, FRAGRANCE, GLYCERYL CAPRYLATE, TOCOPHERYL ACETATE, DISODIUM EDTA, HYDROLYZED COLLAGEN, UBIQUINONE, ACETYL HEXAPEPTIDE-8

Laser Sunscreen 100



# Laser Sunscreen 100 <sub>SPF</sub> 50<sup>+</sup><sub>PA+++</sub>

Providing perfect UV protection Improving skin condition Keeping the skin healthy



### Drug Facts Active Ingredient Purpose Octinoxate (7.5%) Sunscreen Octisalate (5%) -Sunscreen Zinc Oxide (4.8%) Sunscreen Titanium Dioxide (2.49%) 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 when skin is red, inflamed, irritated, or painful When using this product do not use on other parts of the body do not use on damaged or broken skin avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water do not apply directly to wound or open cut Stop use and ask a doctor if Rash or irritation on skin develops and lasts 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 the adequate amount onto the entire face at the last stage of your skin care routine. Re-apply frequently and generously to maintain protection. the palm of the hands and pat lightly with the fingertips. 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 Avoid storing product in direct sunlight. Inactive Ingredients WATER, CYCLOPENTASILOXANE, BUTYLENE GLYCOL, DIPROPYLENE GLYCOL, DICAPRYLYL CARBONATE, PEG-10 DIMETHICONE, LAURYL PEG-8 DIMETHICONE, DIMETHICONE, DISTEARDIMONIUM HECTORITE, MAGNESIUM SULFATE, PHENYL TRIMETHICONE, METHYL METHACRYLATE CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, PHENOXYETHANOL, ALUMINUM HYDROXIDE, ALUMINUM STEARATE, METHICONE, POLYGLYCERYL-6 POLYRICINOLEATE, CAPRYLYL GLYCOL, FRAGRANCE, GLYCERYL CAPRYLATE, TOCOPHERYL ACETATE, DISODIUM EDTA, HYDROLYZED COLLAGEN, UBIQUINONE, ACETYL HEXAPEPTIDE-8 Distributed by Kreassive Llc 22808 Lockness Ave. Torrance CA 90501 USA

# LASER SUNSCREEN 100 octisalate, octinoxate, zinc oxide, titanium dioxide cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:52554-1115 Route of Administration TOPICAL Item Code (Source) NDC:52554-1115 Active Ingredient/Active Moisser TOPICAL Strength Strength

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	$1.75\ g$ in $35\ mL$
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.68 g in 35 mL
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	$0.8715\;g~$ in 35 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.625 g in 35 mL

	Strength			
WATER (UNII: 059QF0	KO0R)			
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)				
BUTYLENE GLYCOL	(UNII: 3XUS85K0RA)			
DISTEARDIMO NIUM	HECTORITE (UNII: X687XDK09L)			
DIPROPYLENE GLYCOL (UNII: E107L85C40)				
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
DIMETHICO NE (UNII:	92RU3N3Y1O)			
Packaging				
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End D	

# Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b> NDC:52554-1115-2	1 in 1 PACKAGE	0 1/16/20 18	
<b>1</b> NDC:52554-1115-1	35 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	0 1/16/20 18		

# Labeler - CMS LAB Inc. (557795012)

## Registrant - CMS LAB Inc. (557795012)

Establishment						
Name	Addres	ess ID/FEI			<b>Business Operations</b>	
CMS LAB Inc.		557795012		relabel(52554-1115)		
Establishment						
Name		Addr	ess	ID/FEI		<b>Business Operations</b>
Kolmar Korea Co., Ltd.				689512611		manufacture(52554-1115)

Revised: 1/2018

CMS LAB Inc.