ULTRA CC RADIANT FOUNDATION BROAD SPECTRUM SPF 17 WARM-TAN- zinc oxide cream Pacifica Beauty, LLC

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.

Ultra CC Radiant Foundation BroadSpectrum SPF 17 Warm-Tan

Active ingredient Purpose

Zinc Oxide 11.4% 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.

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

Do not use on damaged or broken skin.

When using this product

When using this product keep out of eyes. Rinse with water to remove.

STOP USE AND ASK A DOCTOR

STOP USE AND ASK A DOCTOR IF RASH OCCURS.

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply liberally 15 minutes before sun exposure. Use a water resistant sunscreen if

swimming or sweating. Reapply 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 a.m. - 2 p.m. - wear long-sleeve shirts, pants, hats and sunglasses. Children under 6 months: Ask a doctor.

Inactive ingredients:

Water (Aqua), Caprylic/Capric Triglyceride, Sorbitan Sesquioleate, Dimethicone, Potassium Cetyl Phosphate, Glycerin, Silica, Jojoba Esters, Cetearyl Olivate, Sorbitan Olivate, Mica, Citric Acid, Potassium Sorbate, Sodium Dehydroacetate, Sodium Benzoate, Fragrance (All Natural), Sodium Hyaluronate, Cocos Nucifera (Coconut) Water, Withania Somnifera Root Extract, Carthamus Tinctorius (Saffower) Seed Oil, Macrocystis Pyrifera Extract, Linalool, Amyl Cinnamal, Titanium Dioxide Cl 77891, Iron Oxides Cl 77491, Cl 77492, and Cl 77499.

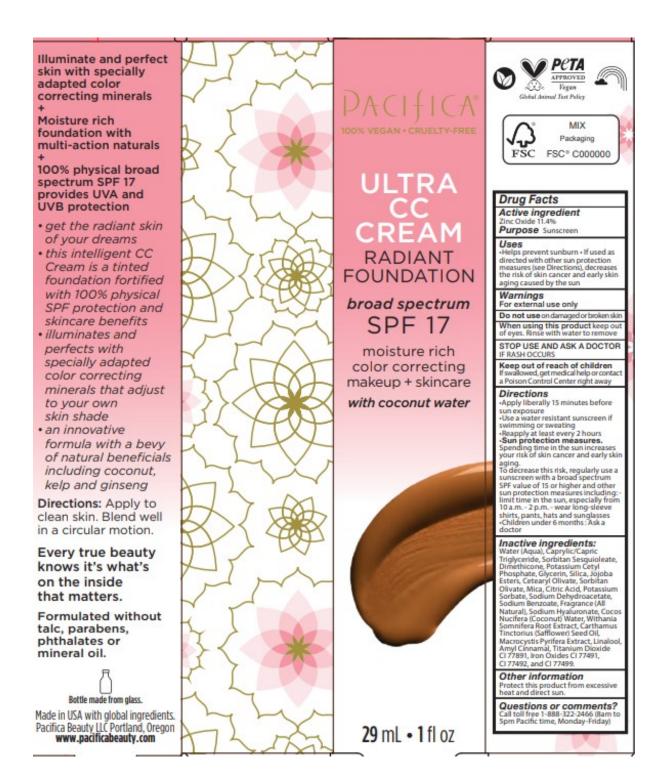
Other information

Protect this product from excessive heat and direct sun.

Questions or comments?

Call toll free 1-888-322-2466 (8am to 5pm Pacific time, Monday-Friday)

Ultra CC Radiant Foundation Broad Spectrum SPF 17 Warm-Tan Label



ULTRA CC RADIANT FOUNDATION BROAD SPECTRUM SPF 17 WARM-TAN

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61197-301
Route of Administration	TOPICAL		
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	11.4 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
COCONUT WATER (UNII: 267F5Y81NT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
MICA (UNII: V8A1AW0880)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.ALPHAAMYLCINNAMALDEHYDE (UNII: WC51CA3418)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WITHANIA SOMNIFERA ROOT (UNII: V038D626IF)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
WATER (UNII: 059QF0KO0R)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:61197- 301-00	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/10/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M020	02/10/2023		
3 1				

Establishment				
Name	Address	ID/FEI	Business Operations	
Columbia Cosmetics Manufacturers, Inc.		068267863	manufacture(61197-301)	

Revised: 2/2023 Pacifica Beauty, LLC