PACIFICA CC BROAD SPECTRUM SPF 17 MEDIUM- 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.

Pacifica CC+ CREAM broad spectrum SPF 17 MEDIUM

Drug Facts

Active ingredient

ZInc Oxide 11.4%

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, 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-sleeved 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, ceteraryl olivate, sorbitan olivate, mica, citric acid, potassium sorbate, sodium dehydroacetate, sodium benzoate, fragrance, sodium hyaluronate, cocos nucifera (coconut) water, withania somnifera root extract, carthamus tinctorius (safflower) seed oil, macrocystis pyrifera extract, linalool, amyl cinnamal, titanium Dioxide, CI 77891, Iron oxides CI 77491, CI 77492, and CI77499

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)

Package Labeling:



PACIFICA CC BROAD SPECTRUM SPF 17 MEDIUM

zinc oxide cream

Product Information								
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC	NDC:61197-001			
Route of Administration	TOPICAL							
Active Ingradient/Active Meistr								
Active Ingredient/Active Moiety								
Ingredient Name			Basis of Strength		Strength			
ZINC OXIDE (UNII: SOI2LOH54Z) (ZIN	COXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE		114 mg in 1 mL			
Inactive Ingredients								

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SORBITAN SESQUIOLEATE (UNII: 0 W8 RRI5W5A)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYL JOJOBATE (UNII: 2351QH8W1N)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
MICA (UNII: V8A1AW0880)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
COCONUT JUICE (UNII: AMN6S4M09G)	
WITHANIA SOMNIFERA ROOT (UNII: V038D626IF)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
MACRO CYSTIS PYRIFERA (UNII: K31S3OG5C4)	
.ALPHAAMYLCINNAMALDEHYDE (UNII: WC51CA3418)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:61197-001- 00	1 in 1 BOX	11/21/2013				
1		30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product					
Marketing Information							
	Marketing Catego	ory Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
0	TC monograph not f	inal part352	11/21/2013				

Labeler - Pacifica Beauty, LLC (058549421)

Establishment

Name	Address	ID/FEI	Business Operations
Columbia Cosmetics Manufacturing, Inc.		068267863	manufacture (6 119 7-0 0 1)