

REPLENISH SPF 40- zinc oxide cream

ELIZA ARAKELIAN

DRUG FACTS

ACTIVE INGREDIENT:

Zinc Oxide 16%

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 aging caused by the sun.

WARNINGS: For external use only. Do not use on damaged or broken skin. Stop use and ask a doctor if rash occurs. When using this product, keep out of eyes. Rinse with water to remove. 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 product if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: Ask a doctor.
- 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 am- 2 pm.
 - Wear long sleeve shirts and hats and sunglasses.

INACTIVE INGREDIENTS: Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicones, Polyhydrosilicic Acid, Tetrahydroxyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Hydrogen Dimethicone Silsesquioxane Crosspolymer

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun.
- May stain some fabrics.

BLUE ORCHID BEAUTY
14567 BIG BASIN WAY D2, SARATOGA, CA 95070 | 408-867-2001

ELIZA ARAKELIAN

BY ELIZA ARAKELIAN

SPF 40 BROAD SPECTRUM
CERAMIDES, ANTI-AGING

REPLENISH
MINERAL SUNSCREEN
TINTED | NONCOMEDOGENIC

1.75 OZ (50g)



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REPLENISH SPF 40

zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85555-208(NDC:58892-208)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	160 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength

TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CI 77492 (UNII: EX438O2MRT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
CI 77499 (UNII: XM0M87F357)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CI 77491 (UNII: 1K09F3G675)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85555-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/04/2020	

Labeler - ELIZA ARAKELIAN (125207466)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85555-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85555-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85555-208)