

GENTLE MINERAL SPF 40 TINTED- zinc oxide cream
ELIZA ARAKELIAN

DRUG FACTS
ACTIVE INGREDIENT: Zinc Oxide 20%
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
• Reapply:
- After 40 minutes of swimming or sweating
- Immediately after towel drying
- 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: Bismuth Oxychloride, Cetearyl Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone Vinyl Dimethicone Crosspolymer, Dimethiconol Disodium EDTA, Glycerin, Iron Oxides, Hydrogen Dimethicones, Mica, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polynonylhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water
OTHER INFORMATION:
- Protect this product from excessive heat and direct sun
- May stain some fabrics.
BLUE ORCHID BEAUTY
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3 85555 20460 9
ELIZA ARAKELIAN
BY ELIZA ARAKELIAN
SPF 40 BROAD SPECTRUM
WATER RESISTANT
GENTLE MINERAL
TINTED | NONCOMEDOGENIC
2.1 OZ

GENTLE MINERAL SPF 40 TINTED			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85555-204(NDC:58892-204)
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	200 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
CI 77491 (UNII: 1K09F3G675)	
CI 77492 (UNII: EX438O2MRT)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
MICA (UNII: V8A1AW0880)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
CI 77499 (UNII: XM0M87F357)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85555-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/22/2019	

Labeler - ELIZA ARAKELIAN (125207466)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85555-204)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc		793406000	manufacture(85555-204)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85555-204)

Revised: 12/2025

ELIZA ARAKELIAN