

BIO H PLUS DAILY DEFENSE AND REVITALIZE- zinc oxide cream
BIOHEALTH PLUS LLC

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-sleeved shirts, pants, 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 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer
OTHER INFORMATION: Protect this product from excessive heat and direct sun. May stain some fabrics.

MANUFACTURED FOR:
Bio Health Plus | Weston, FL 33326
(754) 213-9789



Daily Defense
& Revitalize
Tinted

Broad Spectrum SPF 40

Mineral Sunscreen with
Ceramides & Antioxidants
Protect, Repair & Nourish

Net Wt. 1.75 oz / 50 g

BIO H PLUS DAILY DEFENSE AND REVITALIZE
zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85403-208
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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85403-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/20/2021	

Labeler - BIOHEALTH PLUS LLC (869441449)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85403-208)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85403-208)