

EMME DIANE PURE PROTECTION TINTED ANTIOXIDANT SUNSCREEN- zinc oxide cream

Emme Diane, Inc.

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.

Drug Facts:

Active Ingredients:

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 skin 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 the 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 10:00 am-2:00 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

Principal Display Panel - 50 g Bottle Label**EMME DIANE****PURE****PROTECTION****TINTED ANTIOXIDANT****SUNSCREEN**

SPF 40 BROAD SPECTRUM

NET WT. 1.75 OZ (50 G)

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Distributed by Emme Diane, Inc.
Scottsdale, AZ - www.emmediane.com

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zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81377-208
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
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CERAMIDE NP (UNII: 4370DF050B)	
Cyclomethicone 6 (UNII: XHK3U310BA)	

Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone 20 (UNII: H8YMB5QY0D)	
Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane) (UNII: UF7620L1W6)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)	
Dimethiconol (2000 CST) (UNII: T74O12AN6Y)	
Brown Iron Oxide (UNII: 1N032N7MFO)	
Hydrogen Dimethicone (20 CST) (UNII: 12Z59IF64N)	
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81377-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2022	

Labeler - Emme Diane, Inc. (116110568)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(81377-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(81377-208) , PACK(81377-208)

Revised: 1/2023

Emme Diane, Inc.