MILANI SPF BFF 30 PRIMER- avobenzone, octinoxate, octocrylene, oxybenzone cream New Milani Group, LLC

Milani SPF BFF 30 Primer

Drug Facts

Active ingredients

Avobenzone 3%, Octinoxate 7.3% Octocrylene 3% Oxybenzone 2%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see), decreases the risk of skin cancer and early skin aging caused by the sun *Directions*

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 generously and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating

- children under 6 months of age: Ask a doctor.
- 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: Sun Protection
 Measures.
- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeved shirts, pants, and sunglasses

Other information

Protect the product in this container from excessive heat and direct sun

Inactive ingredients:

Water, Glycerin, Isohexadecane, Sodium Acrylate/ Sodium Acryloyldimethyl Taurate Copolymer, PEG-8, Polysorbate 80, Xanthan Gum, Tocopherol, Glycine Soja (Soybean) Oil, Retinyl Palmitate, Ethylhexylglycerin, Citric Acid, Disodium EDTA, Phenoxyethanol, Yellow 5, Red 40.

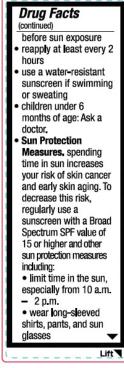
Questions or comments?

Call 866-789-8002 Monday - Friday (7 a.m. to 3:30 p.m. PST)

Package Labeling:













MILANI SPF BFF 30 PRIMER

avobenzone, octinoxate, octocrylene, oxybenzone cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71435-0001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	73 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	30 mg in 1 mL		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	20 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
SODIUM ACRYLATE (UNII: 7C98FKB43H)	
SODIUM ACRYLOYLDIMETHYLTAURATE (UNII: 2T9Q6EKI0G)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SOYBEAN OIL (UNII: 241ATL177A)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:71435- 0001-0	30 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2020	

Labeler - New Milani Group, LLC (120923342)