

MILANI PRIME PROTECT SPF 30 FACE PRIMER- avobenzene, octinoxate, octocrylene, and oxybenzone cream

The Milani Group, 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.

Milani Prime Protect SPF 30 Face Primer

Drug Facts

Active Ingredients	Purpose
Avobenzene 3.0%	Sunscreen
Octinoxate 7.3%	Sunscreen
Octocrylene 3.0%	Sunscreen
Oxybenzone 2.0%	Sunscreen

Uses

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

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

For Sunscreen use:

- Apply generously and evenly 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in 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 a.m. – 2 p.m.
 - Wear long-sleeved shirts, pants, and sun glasses

- Children under 6 months of age: Ask a doctor.

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, phenoxyethanol, polysorbate 80, xanthan gum, tocopherol, ethylhexylglycerin, citric acid, retinyl palmitate, disodium EDTA, glycine soja (soybean) oil, yellow 5 (CI 19140), red 40 (CI 16035).

Questions or comments?

Call 866-789-8002 Monday - Friday (8 a.m. to 5 p.m. PST)

PRINCIPAL DISPLAY PANEL - 30 mL Tube Carton

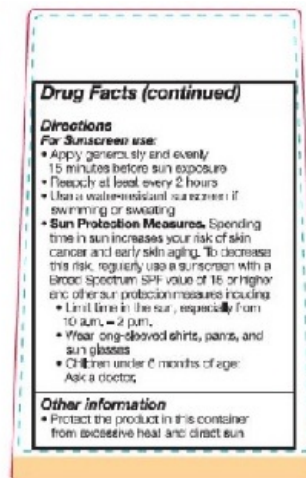
MILANI

PRIME
PROTECT

SPF 30 FACE PRIMER

BROAD SPECTRUM SUNSCREEN
+ UVA/UVB PROTECTION

1 FL OZ / 30 mL



MILANI PRIME PROTECT SPF 30 FACE PRIMER

avobenzone, octinoxate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71435-8202
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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TOCOPHEROL (UNII: ROZB2556P8)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
SOYBEAN OIL (UNII: 241ATL177A)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71435-8202-6	1 in 1 CARTON	11/25/2017	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/25/2017	

Labeler - The Milani Group, Inc. (120923342)

Revised: 11/2022

The Milani Group, Inc.