

FACIAL NATURAL MINERAL SUNSCREEN BROAD SPECTRUM SPF 30- zinc oxide lotion
Crossing Cultures LLC dba Goddess Garden

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.

Facial Natural Mineral Sunscreen Broad Spectrum SPF 30 Lotion

Drug Facts

Active Ingredients

Zinc Oxide 19.0%

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 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. • At least every 2 hours. • Children under 6 months of age: 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 10am to 2pm. • Wear long-sleeved shirts, pants, hats and sunglasses.

Other Information

• Protect this product from excessive heat and direct sun. • Store at temperatures below 90°F. • **May**

stain some fabrics or surfaces.

Inactive Ingredients

Aloe Barbadensis Leaf Juice*, Butyrospermum Parkii (Shea Butter), Caprylhydroxamic Acid, Carthamus Tinctorius (Safflower) Seed Oil*, Glycerin, Glyceryl Caprylate, Glyceryl Stearate Citrate, Helianthus Annuus (Sunflower) Seed Oil*, Helichrysum Italicum (Immortelle) Oil, Lavandula Angustifolia (Lavender) Oil, Lavandula Hybrida (Lavender) Oil*, Polyhydroxystearic Acid, Sorbitan Oleate, Tocopherol (Vitamin E), Water, Xanthan Gum ***Certified Organic**

Questions or Comments

Toll-free 1-855-SAFE-SUN or
www.GoddessGarden.com

Package Labeling:

After discovering our daughter was sensitive to synthetic chemicals, we were inspired to create better alternatives. Today, we make sunscreens that are safe, effective and good for the Earth.

Nova & Paul, Founders *Nova Paul*

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FACIAL NATURAL MINERAL SUNSCREEN BROAD SPECTRUM SPF 30

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58479-031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SHEA BUTTER (UNII: K49155WL9Y)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
HELICHRYSUM ITALICUM FLOWER OIL (UNII: O97ZV7726K)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LAVANDIN OIL (UNII: 9RES347CKG)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58479-031-00	28 g in 1 TUBE; Type 0: Not a Combination Product	01/16/2016	
2	NDC:58479-031-01	96 g in 1 TUBE; Type 0: Not a Combination Product	01/16/2016	
3	NDC:58479-031-02	6 g in 1 PACKET; Type 0: Not a Combination Product	01/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/16/2016	

Labeler - Crossing Cultures LLC dba Goddess Garden (078444606)**Registrant** - Crossing Cultures LLC dba Goddess Garden (078444606)