

PURPLE SUNBLOCK- zinc oxide cream
Iruri Nature Handmade Soap & Cosmetic 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.

Purple Sunblock (Grape seed & Argan oil Sunblock)

Active Ingredients

Zinc oxide (8%)

Purpose

Sunscreen

Uses

Helps prevent sunburn

Warnings

For external use only

Do not use when skin is red, inflamed, irritated, or painful

When using this product

- do not apply on other parts of the body
- do not use on damaged or broken skin
- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water
- do not apply directly to wound or open cut

Stop use and ask a doctor if

- Rash or irritation on skin develops and lasts

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

1. Apply the adequate amount on the palm of the hands and pat lightly with the fingertips.
2. Apply liberally 15 minutes before sun exposure.
3. Reapply at least every 2 hours.
4. Use a water-resistant sunscreen if swimming or sweating.
5. 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:

- 1) Limit time in the sun, especially from 10 a.m.- 2 p.m.
- 2) Wear long-sleeved shirts, pants, hats, and sunglasses.
6. Children under 6 months of age: ask a doctor

Inactive Ingredients

Castor oil, Grape seed oil, Argan oil, Allantoin, Emulsifying wax, Distilled water, Lavender water, Glycerin, Vitamin E oil, Optiphen plus

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 - Wear long-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months of age: ask a doctor

Other information

- Avoid storing product in direct sunlight.

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**Manufactured by Iruri Nature
Handmade Soap & Cosmetic Inc.**

17908 Woodruff Ave Apt 51, Bellflower, CA
90706

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71547-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.6 g in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ARGAN OIL (UNII: 4V59G5UW9X)	
CASTOR OIL (UNII: D5340Y2I9G)	
WATER (UNII: 059QF0K00R)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
ALLANTOIN (UNII: 344S277G0Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71547-111-02	1 in 1 PACKAGE	07/25/2017	
1	NDC:71547-111-01	20 mL in 1 CONTAINER; 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	07/25/2017	

Labeler - Iruri Nature Handmade Soap & Cosmetic Inc (095675041)

Registrant - Iruri Nature Handmade Soap & Cosmetic Inc (095675041)

Establishment

Name	Address	ID/FEI	Business Operations
Iruri Nature Handmade Soap & Cosmetic Inc		095675041	manufacture(71547-111)