EM SHEA BUTTER CREAM- shea butter cream Iruri Nature Handmade Soap & Cosmetic Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

EM Shea Butter Cream

Active Ingredients

Shea Butter (25.7%)

Purpose

Skin protectant

Keep out of reach of children

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

Uses

Moisturizes skin.

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
- 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

Directions

After cleansing face, apply the adequate amount on skin.

Inactive ingredients

Coconut oil, Castor oil, Bees wax, Cocoa butter, Emulsifying wax, Distilled water, E.M, Lavender essential oil, Vitamin E oil, Optiphen plus

EM Shea Butter Cream

Drug Facts

Active Ingredient Purpose

Shea butter (25.7%) ----- Skin Protectant

Uses Moisturizes skin. Helps to reduce the wrinkles.

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
- 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

After cleansing face, apply the adequate amount on skin.

Other information

Avoid storing product in direct sunlight.

Inactive Ingredients Coconut oil,

Castor oil, Bees wax, Cocoa butter, Emulsifying wax, Distilled water, E.M, Lavender essential oil, Vitamin E oil, Optiphen plus

Manufactured by Iruri Nature Handmade Soap & Cosmetic Inc.

17908 Woodruff Ave Apt 51, Bellflower, California (CA) 90708

EM SHEA BUTTER CREAM

shea butter cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71547-102

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
SHEA BUTTER (UNII: K49155WL9Y) (SHEA BUTTER - UNII:K49155WL9Y)
SHEA BUTTER
5.14 g in 20 mL

Inactive Ingredients

WATER (UNII: 059QF0KO0R)

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
COCOA BUTTER (UNII: 5120 YT1CRR)	
.ALPHATO COPHEROL (UNII: H4N855PNZ1)	
COCONUT OIL (UNII: Q9L0O73W7L)	
CASTOR OIL (UNII: D5340 Y2I9 G)	

LAVENDER OIL (UNII: ZBP1YXW0H8)

Ш	Packaging							
II	# Item Code	Package Description	Marketing Start Date	Marketing End Date				
	1 NDC:71547-102- 02	1 in 1 PACKAGE	07/13/2017					
	1 NDC:71547-102-01	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		
unapproved drug other		07/13/2017			

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

$\pmb{Registrant - \text{Iruri Nature Handmade Soap \& Cosmetic Inc (095675041)}}$

Establishment					
Name	Address	ID/FEI	Business Operations		
Iruri Nature Handmade Soap & Cosmetic Inc		095675041	manufacture(71547-102)		

Revised: 7/2017 Iruri Nature Handmade Soap & Cosmetic Inc