

MARGARITE ZINC CREAM- zinc cream cream
Renu Laboratories, 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.

MARGARITE ZINC CREAM

Active ingredient

Sulfur 4%

Do not use on

- broken skin
- large areas of the skin
- eyes and mouth

Purpose

Acne Treatment

1.800.644.1466

If excessive skin irritation develops or increases, discontinue use and consult a doctor.

When Using this Product

- apply only to areas with acne
- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time.
- If irritation occurs, only use one topical acne medication at a time.

Warnings

For external use only

- Keep out of the reach of children.

Inactive Ingredients:

Water, Zinc Oxide (10%), Cetearyl Alcohol, Cetearyl Alcohol, Cetearth-20, Cetyl Alcohol, Glyceryl Stearate, Titanium Dioxide, Vegetable Oil (Castor), Hydrogenated Vegetable Oil (Castor), Euphorbia Cerifera (Candelilla) Wax, Ricinus Communis (Castor) Seed Oil, Bentonite, Phenoxyethanol, Iron Oxides.

Directions

- Cleanse the skin thoroughly before applying ZINC CREAM FOR PROBLEM SKIN.
- Cover the entire affected area up to three times daily
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day. ZINC CREAM FOR PROBLEM SKIN can be used under make-up or

moisturizer.

Uses

- **treats acne**
- **dries up acne pimples**
- **helps prevent new acne pimples**

TINTED MINERAL FORMULA

FRAGRANCE FREE, PARABEN FREE

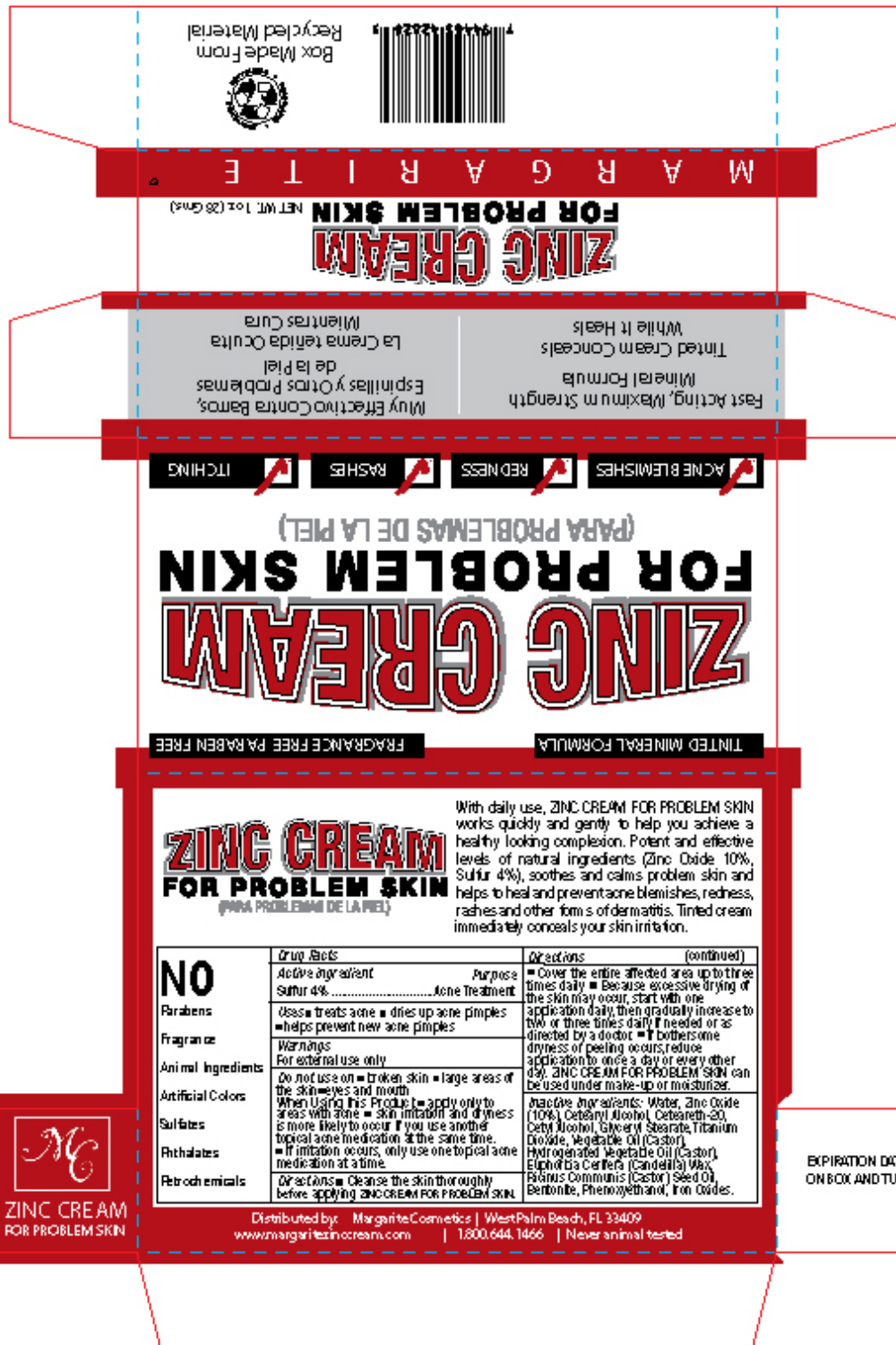
ZINC CREAM
FOR PROBLEM SKIN
 (PARA PROBLEMAS DE LA PIEL)

- BLEMISHES**
- REDNESS**
- RASHES**
- ITCHING**

NET WT. 1oz. (28g)

M A R G A R I T E

Drug Facts		Drug Facts (continued)	Drug Facts (continued)
Active ingredient Sulfur 4%	Purpose Acne Treatment	If Irritation occurs, only use one topical acne medication at a time.	Inactive Ingredients Water, Zinc Oxide (10%), Cetearyl Alcohol, Ceteareth-20, Cetyl Alcohol, Glyceryl Stearate, Titanium Dioxide, Vegetable Oil (Castor), Hydrogenated Vegetable Oil (Castor), Euphorbia Cerifera (Candelilla) Wax, Ricinus Communis (Castor) Seed Oil, Bentonite, Phenoxyethanol, Iron Oxides.
Uses = treats acne = dries up acne pimples = helps prevent new acne pimples		Directions = Cleanse the skin thoroughly before applying ZINC CREAM FOR PROBLEM SKIN. = Cover the entire affected area up to three times daily. = Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. = If bothersome dryness or peeling occurs, reduce application to once a day or every other day. ZINC CREAM FOR PROBLEM SKIN can be used under make-up or moisturizer.	Distributed by: Margarite Cosmetics West Palm Beach, FLA 33409 www.margaritezinccream.com 1.800.644.1466
Warnings For external use only			
Do not use on = broken skin = large areas of the skin = eyes and mouth When using this product = apply only to areas with acne = skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time.			



Box Made From Recycled Material



M A R G A R I T E

ZINC CREAM
FOR PROBLEM SKIN
NET WT. 1.01 (28 gms)

Fast Acting, Maximum Strength Mineral Formula
Tinted Cream Conceals While It Heals

Muy Efectivo Contra Bamos, Espinillas y Otros Problemas de la Piel
La Crema tñida Oculta Mientras Cura

ACNE BLEMISHES REDNESS RASHES ITCHING

ZINC CREAM
FOR PROBLEM SKIN
(PARA PROBLEMAS DE LA PIEL)

TINTED MINERAL FORMULA FRAGRANCE FREE PARABEN FREE

ZINC CREAM
FOR PROBLEM SKIN
(PARA PROBLEMAS DE LA PIEL)

With daily use, ZINC CREAM FOR PROBLEM SKIN works quickly and gently to help you achieve a healthy looking complexion. Potent and effective levels of natural ingredients (Zinc Oxide 10%, Sulfur 4%), soothes and calms problem skin and helps to heal and prevent acne blemishes, redness, rashes and other forms of dermatitis. Tinted cream immediately conceals your skin irritation.

NO	Drug Facts	Directions (continued)
Parabens	Active ingredient Sulfur 4%.....Acne Treatment	• Cover the entire affected area up to three times daily • Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • If bothersome dryness or peeling occurs, reduce application to once a day or every other day. ZINC CREAM FOR PROBLEM SKIN can be used under make-up or moisturizer.
Fragrance	Warnings For external use only	
Animal Ingredients	Do not use on • broken skin • large areas of the skin • eyes and mouth	
Artificial Colors	When Using This Product • apply only to areas with acne • skin irritation and if stings is more likely to occur if you use another topical acne medication at the same time.	
Sulfates	• If irritation occurs, only use one topical acne medication at a time.	
Ritralates	Directions • Cleanse the skin thoroughly before applying ZINC CREAM FOR PROBLEM SKIN.	
Retinohemials		Inactive ingredients: Water, Zinc Oxide (10%), Cetearyl Alcohol, Ceteareth-20, Cetyl Alcohol, Glycerol Stearate, Titanium Dioxide, Vegetable Oil (Castor), Hydrogenated Vegetable Oil (Castor), Ethyl Dia Carbons (Candelilla) Wax, Palmitus Communis (Castor) Seed Oil, Bentonite, Phenoxylethanol, Iron Oxides.



EXPIRATION DATE ON BOX AND TUBE

Distributed by: Margarite Cosmetics | West Palm Beach, FL 33409
www.margariteincosmetics.com | 1.800.644.1466 | Never animal tested

MARGARITE ZINC CREAM			
zinc cream cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76348-413

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	1.12 g in 28 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	20.7 g in 28 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROUS OXIDE (UNII: G7036X8B5H)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
BENTONITE (UNII: A3N5ZCN45C)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CASTOR OIL (UNII: D5340Y2I9G)	
CANDELILLA WAX (UNII: WL0328HX19)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76348-413-02	1 in 1 BOX	10/13/2015	
1	NDC:76348-413-01	28 g 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 final	part333D	10/13/2015	

Labeler - Renu Laboratories, Inc. (945739449)

Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-413)

Revised: 1/2022

Renu Laboratories, Inc.