

ROCCOS OLD SCHOOL HEALING BALM- zinc oxide cream

Roccas Old School

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.

Drug Facts

Active Ingredient: Purpose:

Zinc Oxide 3%.....Skin Protectant

Use:

- To promote healing of minor skin irritations and sunburn.

Warnings:

For external use only-skin. Flammable. Keep away from heat and flame.

When using this product

- Avoid contact with the eyes. In case of contact with eyes, flush thoroughly with water.

Stop use and ask a doctor if

condition worsens or does not improve.

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center Immediately.

Directions

- Apply balm liberally as often as necessary.

Other information

- Store at controlled room temperature.
- Do not store above 105°F.

Inactive ingredients

Mangifera Indica (Mango) Seed Butter, Cocos Nucifera (Coconut) Oil, Butyrospermum Parkii (Shea Butter) Fruit, Beeswax, Agave Americana Leaf Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Cannabis Sativa (Hemp) Seed Oil, Persea Gratissima (Avocado) Oil, Caprylic/Capric Triglyceride (and) Glycerol Isostearate (and) Polyhydroxystearic Acid, and Natural Fragrance

Questions?

661-877-4280

Placeholder Text



Roccos_Can Lid



Roccos_Can Bottom

ROCCOS OLD SCHOOL HEALING BALM			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24488-010
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	.9 mL in 30 mL	
Inactive Ingredients			
Ingredient Name	Strength		
MANGIFERA INDICA SEED BUTTER (UNII: 40XD9M35X2)			
COCONUT OIL (UNII: Q9L0O73W7L)			
SHEANUT (UNII: 84H6HBP32L)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
AGAVE AMERICANA LEAF (UNII: 8511ZMP5QK)			
JOJOBA OIL (UNII: 724GKU717M)			
TEA TREE OIL (UNII: VIF565UC2G)			

CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
COCONUT (UNII: 3RT3536DHY)	
LIME (UNII: C7X2M0VVNH)	
VERBENA HASTATA ROOT (UNII: LJ96XN173E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24488-010-10	30 mL in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/17/2011	

Labeler - Roccas Old School (961956229)

Registrant - Creations Garden Natural Products Inc. (961956229)

Establishment

Name	Address	ID/FEI	Business Operations
Creations Garden Natural Products Inc.		961956229	manufacture

Revised: 2/2011

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