

VITABATH BABY SOOTHING RELIEF DIAPER RASH- zinc oxide cream
Vitabath 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.

Vitabath Baby Soothing Relief Diaper Rash Cream

Active Ingredients

Zinc Oxide 14% w/w

Purpose

Skin protectant

Uses

Uses: •helps treat and prevent diaper rash •protects chafed skin due to diaper rash •helps seal out wetness

Warnings

For external use only.

When using this product •avoid contact with eyes

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Stop use and ask a doctor if •condition worsens or does not improve within 7 days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: Change wet or soiled diapers promptly. Clean the diaper area and allow to dry. Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or any time exposure to wet diapers may be prolonged.

Other Information: •Remove quality seal. •Do not use if quality seal is broken.

Inactive Ingredients: Helianthus Annuus (Sunflower) Seed Oil, Beeswax white, Ricinus Communis (Castor) Seed Oil, Butyrospermum Parkii (Shea) Butter, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Tocopherol, Salvia Sclarea (Clary) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Vitis Vinifera (Grape) Seed Oil, Avena Sativa (Oat) Kernel Oil, Calophyllum Inophyllum Seed Oil.

Questions? Call toll-free 1-888-673-3377



VITABATH BABY SOOTHING RELIEF DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73172-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TAMANU OIL (UNII: JT3LVK84A1)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
WHITE WAX (UNII: 7G1J5DA97F)	
CASTOR OIL (UNII: D5340Y2I9G)	
SHEA BUTTER (UNII: K49155WL9Y)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CLARY SAGE OIL (UNII: 87L0D4U3M0)	
JOJOBA OIL (UNII: 724GKU717M)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73172-004-01	113 g in 1 TUBE; Type 0: Not a Combination Product	06/13/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/13/2019	

Labeler - Vitabath Inc. (203461637)**Establishment**

Name	Address	ID/FEI	Business Operations
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Canadian Custom Packaging Company		207062514	manufacture(73172-004)
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Revised: 6/2019

Vitabath Inc.