

DERMOGEN- zinc oxide cream
KRAMER NOVIS

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.

DERMOGEN (Zinc Oxide Cream)

Drug Facts

Active ingredient

Zinc Oxide 15.25%

Purpose

Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash and helps seal out wetness

Warning

☐ **For external use only.**

When using this product • do not get into eyes

Stop and ask a doctor if • condition worsens • symptoms lasts more than 7 days or clear up and occur again within a few 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. • cleanse the diaper area • allow to dry • apply cream liberally as often as necessary, with each diaper, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Inactive ingredients

Butylhydroxytoluene, diazolidinyl urea, fragrance, methylparaben, mineral oil, propylene glycol, propylparaben, Vitamin A, Vitamin D, Vitamin E and white petrolatum.

Other information

• Store at controlled room temperature 15°-30°C (59°-86°F) • **Do not use if seal is broken**

For the Treatment & Prevention of Diaper Rash

Contains the same active ingredient as Dermocrem®

Manufactured in the USA for Kramer Novis,
 San Juan, PR 00917. T: (787) 767-2072.
 www.kramernovis.com

Dermocrem® is a registered trademark of Forest Tosara Ltd. This product is not manufactured, distributed or marketed by Forest Tosara Ltd.

Packaging

<p>Drug Facts</p> <p>Active ingredient Zinc Oxide 15.25%.....PurposeSkin protectant</p> <p>Uses</p> <ul style="list-style-type: none"> • helps treat and prevent diaper rash • protects chafed skin due to diaper rash and helps seal out wetness <p>Warning • For external use only.</p> <p>When using this product • do not get into eyes</p> <p>Stop and ask a doctor if • condition worsens • symptoms lasts more than 7 days or clear up and occur again within a few days</p> <p>Lot. # Exp. Date Rev-03/18</p> <p>UNVARNISHED AREA</p>  <p>52083-68004 5</p>	<p>NDC 52083-680-04</p> <p>DERMOGEN®</p> <p>Zinc Oxide 15.25%</p> <p>Skin Protectant Cream</p> <p>For the Treatment & Prevention of Diaper Rash</p> <p>Contains the same active ingredient as Dermocrem®</p> <p>Net contents: 4 oz. (113.4 g)</p> 	<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> • change wet or soiled diapers promptly • cleanse the diaper area • allow to dry • apply cream liberally as often as necessary, with each diaper, especially at bedtime or anytime when exposure to wet diapers may be prolonged <p>Inactive ingredients Butylhydroxytoluene, diazolidinyl urea, fragrance, methylparaben, mineral oil, propylene glycol, propylparaben, Vitamin A, Vitamin D, Vitamin E and white petrolatum.</p> <p>Other information • Store at controlled room temperature 15°-30°C (59°-86°F) • Do not use if seal is broken</p> <p>Manufactured in the USA for Kramer Novis, San Juan, PR 00917. T: (787) 767-2072. www.kramernovis.com</p> <p>Dermocrem® is a registered trademark of Forest Tosara Ltd. This product is not manufactured, distributed or marketed by Forest Tosara Ltd.</p>
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DERMOGEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52083-680
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15.25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
VITAMIN A (UNII: 81G40H8B0T)	
VITAMIN D (UNII: 9VU1KI44GP)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white	Score	
Shape		Size	

Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52083-680-04	113.4 g in 1 JAR; Type 0: Not a Combination Product	04/04/2016	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	04/04/2016		

Labeler - KRAMER NOVIS (090158395)

Revised: 11/2018

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