

**BIODCREAM- zinc oxide cream**  
**Advanced Generic Corporation**

*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.*

**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

**Warnings**

For external use only.

- When using this product avoid contact with eyes.
- Stop use and ask doctor if condition worsens or lasts more than 7 days

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

**Directions**

- Change wet or soiled diaper promptly
- Cleanse the diaper area and allow to dry
- Apply Cream liberally as often as necessary, with each diaper change, especially at bedtime or when exposure to wet diapers may be prolonged.

**Inactive ingredients**

beeswax, butylated hydroxyl anisole, diazolidinyl urea, lanolin oil, lavender fragrance, methylparaben, paraffinum liquidum, propylene glycol, propylparaben, white petrolatum.

**Questions or comments :**

1-305-403-3788

<p><b>Drug Facts</b></p> <table border="1"><tr><td><b>Active ingredient</b> Zinc Oxide 15.25%</td><td><b>Purpose</b> Skin Protectant</td></tr></table> <p><b>Uses:</b> •helps treat and prevent diaper rash. • protects chafed skin due to diaper rash and helps seal out wetness</p> <p><b>Warnings:</b> •For external use only. •When using this product avoid contact with eyes. •Stop use and ask doctor if condition worsens or last more than 7 days. • Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center immediately.</p> <p>†Dermocrem® is a registered trademark of Forest Tosara Ltd. This product is not manufactured, distributed or marketed by Forest Tosara Ltd.</p> <p>Lot #: _____ Rev. 02/17 Exp. Date: _____</p>	<b>Active ingredient</b> Zinc Oxide 15.25%	<b>Purpose</b> Skin Protectant	<p style="text-align: center;">NDC 45737-701-04</p> <h1 style="text-align: center;">BIODcream®</h1> <p style="text-align: center;">Zinc Oxide Diaper Rash Cream Protects against: •Diaper Wetness •Skin Chafing</p> <p style="text-align: center;">FOR EXTERNAL USE ONLY. DO NOT USE IN EYES.</p> <p style="text-align: center;">Contains the same active ingredients as Dermocrem®.</p> <p style="text-align: center;">Manufactured For:  advanced generic corporation Miami, FL 33147 www.advancedgeneric.com</p> <p style="text-align: center;">Contents 4.4 fl. oz. (125g)</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Directions:</b> •Change wet or soiled diaper promptly • Cleanse the diaper area and allow to dry • Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or when exposure to wet diapers may be prolonged.</p> <p><b>Other information:</b> • Do not use if seal is torn, broken or missing. • Store at controlled room 25°-30°C (59°-86°F).</p> <p><b>Inactive ingredients:</b> beeswax, butylated hydroxyl anisole, diazolidinyl urea, lanolin oil, lavender fragrance, methylparaben, paraffinum liquidum, propylene glycol, propylparaben, white petrolatum.</p> <p><b>Questions and comments?</b> 1-305-403-3788</p> <p><b>Manufactured For:</b> Advanced Generic Corporation, Miami, FL 33147 www.advancedgeneric.com</p>
<b>Active ingredient</b> Zinc Oxide 15.25%	<b>Purpose</b> Skin Protectant			



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NDC 45737-701-04

**BIODcream**<sup>®</sup>

Zinc Oxide Diaper Rash Cream

Protects against:

• Diaper Wetness • Skin Chafing

FOR EXTERNAL USE ONLY. DO NOT USE IN EYES.

Contains the same active ingredients as Dermocrem<sup>®</sup>.

Manufactured For:



advanced generic corporation  
Miami, FL 33147  
www.advancedgeneric.com

Contents  
4.4 fl. oz. (125g)

**Drug Facts** (continued)

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

**Other information:** • Do not use if seal is torn, broken or missing • Store at controlled room 25°-30°C (69°-86°F).

**Inactive ingredients:** beeswax, butylated hydroxytoluene, diazolidinyl urea, lanolin oil, lavender fragrance, methylparaben, paraffinum liquidum, propylene glycol, propylparaben, white petrolatum.

**Questions and comments?** 1-305-403-3788

**Manufactured For:** Advanced Generic Corporation, Miami, FL 33147  
www.advancedgeneric.com

**Drug Facts**

**Active ingredient** *Purpose*  
Zinc Oxide 15.25%.....Skin Protectant

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Lot #: \_\_\_\_\_ Rev. 02/17  
Exp. Date: \_\_\_\_\_

**BIODCREAM**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:45737-701
<b>Route of Administration</b>	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
YELLOW WAX (UNII: 2ZA36H0S2V)	
MINERAL OIL (UNII: T5L8T28FGP)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
LANOLIN OIL (UNII: OVV5IJJ58F)	
PETROLATUM (UNII: 4T6H12BN9U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45737-701-04	125 g in 1 JAR; Type 0: Not a Combination Product	04/01/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/01/2016	

**Labeler** - Advanced Generic Corporation (831762971)

