

A AND A DIAPER RASH CREAM - dimethicone and zinc oxide cream
BioZone 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.

Drug Facts

Active ingredients	Purpose
Dimethicone 1%	Diaper rash Cream
Zinc Oxide 10%	Diaper rash Cream

Uses

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

Warnings

For external use only

When using this product

- do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last 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 and soiled diapers promptly
- cleanse the diaper area, and allow to dry
- apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other information

store between 20°C to 25 °C (68° to 77°F)

Inactive Ingredients

Aloe barbadensis extract, benzyl alcohol, coconut oil, cod liver oil (contains vitamin A & Vitamin D), fragrance, glyceryl oleate, light mineral oil, ozokerite, paraffin, propylene glycol, sorbitol, synthetic beeswax, water

Principal Display Panel


A+A Diaper Rash Cream

with DIMETHICONE AND ZINC OXIDE

Helps treat and calm diaper rash

Allows Skin to heal naturally

NDC 55379-407-04



Diaper Rash Cream
with DIMETHICONE AND ZINC OXIDE

- Helps treat & calm diaper rash
- Allows skin to heal naturally

NET WT. 4OZ. (113g) moisturizing with **ALOE**

Drug Facts	
Active Ingredients	Purpose
Dimethicone 1%	Diaper rash cream
Zinc oxide 10%	Diaper rash cream
Uses	
<ul style="list-style-type: none"> ■ Helps treat and prevent diaper rash ■ Protects minor skin irritation due to diaper rash and helps seal out wetness 	
Warnings For external use only	
When using this product ■ do not get in eyes	
Stop use and ask doctor	
<ul style="list-style-type: none"> ■ condition worsens ■ symptoms last more than 7 days or clear and occur again within a few days 	
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center.	

Drug Facts (continued)	
Directions	
<ul style="list-style-type: none"> ■ Change wet and soiled diapers promptly ■ Cleanse the diaper area and allow it to dry ■ apply cream liberally as often as necessary, with each diaper change, especially at bedtime or any time wet diapers may be prolonged 	
Other Information	
Store between 20° to 35°C (68° to 77°F)	
Inactive Ingredients Aloe barbadensis (Aloe Vera) Leaf Extract, Beeswax, Dimethicone, Caprylyl Glycol, Carthamus tinctorius (Safflower) Seed Oil, Cholesterol, Ethylhexyl Glycerin, Fragrance, Glycerin, Hexylene Glycol, Mineral Oil, PEG-100 Stearate, Phenoxyethanol, Potassium Sorbate, Purified Water, Retinyl Palmitate, Sorbitan Stearate, Tocopheryl Acetate, Xanthan Gum	
Distributed by A & A Pharmaceuticals,®	MADE IN USA BioZone Pharmaceuticals, Inc.®

A+A Diaper Rash Cream

A AND A DIAPER RASH CREAM

dimethicone and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55379-407
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	10 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

YELLOW WAX (UNII: 2ZA36H0S2V)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SAFFLOWER OIL (UNII: 65UEH262IS)
CHOLECALCIFEROL (UNII: 1C6V77QF41)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
GLYCERIN (UNII: PDC6A3C0OX)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
MINERAL OIL (UNII: T5L8T28FGP)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
WATER (UNII: 059QF0K00R)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55379-407-04	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part347	06/15/2013	

Labeler - BioZone Laboratories, Inc. (555564293)

Establishment

Name	Address	ID/FEI	Business Operations
Bio Zone Laboratories, Inc.		555564293	manufacture(55379-407)

Revised: 7/2013

BioZone Laboratories, Inc.