# 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.

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#### **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

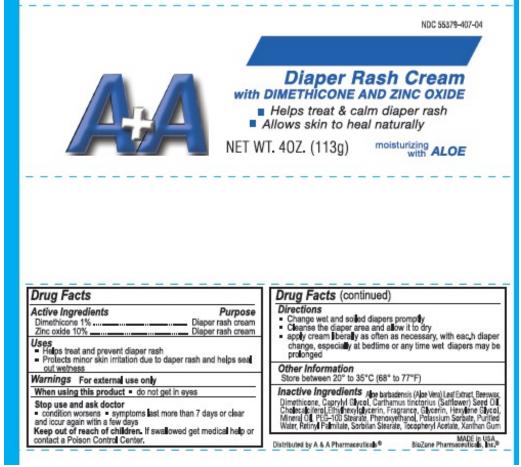
#### **Principal Display Panel**

A+A Diaper Rash Cream

#### with DIMETHICONE AND ZINC OXIDE

Helps treat and calm diaper rash

Allows Skin to heal naturally



#### 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		
<b>DIMETHICO NE</b> (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: 00 YIU5438 U)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
CHOLECALCIFEROL (UNII: 1C6 V77QF41)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	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.