

AKIN DIAPER RASH- zinc oxide gel
Southern Sales & Service, 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.

Active Ingredients

Active Ingredient	Purpose
Zinc Oxide 5%.....	Skin Protectant

INACTIVE INGREDIENT

Purified Water, cyclotetrasiloxane , Isopropyl palmitate, Ethylhexyl palmitate, Glycerin, Cyclopentasiloxane, Polyglyceryl-4 Isostearate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Dimethicone, Tocopherol (Vitamin E), Zea Mays Oil, Retinyl palmitate(Vitamin A), Cholecalciferol (Vitamin D), Beeswax, Hydrogenated Castor Oil, Sodium Chloride, DMDM Hydantoin.

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

INDICATIONS & USAGE

Helps treat and prevent diaper rash.

WARNINGS

For external use only. When using this product avoid contact with 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.

DOSAGE & ADMINISTRATION

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

PURPOSE

- Helps treat and prevent diaper rash.
- Protects chafed skin associated with diaper rash and helps protect from wetness.

Akin Diaper Rash

NDC# 69822-001-06



Diaper Rash Cream

Formula Skin Protectant

Non-Greasy
Fragrance Free
Paraben Free

Net Wt 6 oz
(117 mL)

Drug Facts

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Zinc Oxide 5.0 %	Skin Protectant

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

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Distributed by
Southern Sales Services Inc.
Pembroke Pines FL 33332

Questions or Comments?
Call 1800.213.9370



AKIN DIAPER RASH

zinc oxide gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69822-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DMDM HYDANTOIN (UNII: BYR0546TOW)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
CORN OIL (UNII: 8470G57WFM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MONOPHENYLHEPTAMETHYLCYCLOTETRAILOXANE (UNII: 50Q464790P)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69822-001-06	117 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/25/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/01/2019	

Labeler - Southern Sales & Service, Inc. (013114906)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	manufacture(69822-001)

Revised: 4/2019

Southern Sales & Service, Inc.