

PRESTO- zinc oxide cream
GADAL 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.

ACTIVE INGREDIENT

Active ingredient	Purpose
Zinc Oxide 5.0 %	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.

PRESTO

Distributed by:
Drylock Technologies Ltd.

3921 North Hastings Way

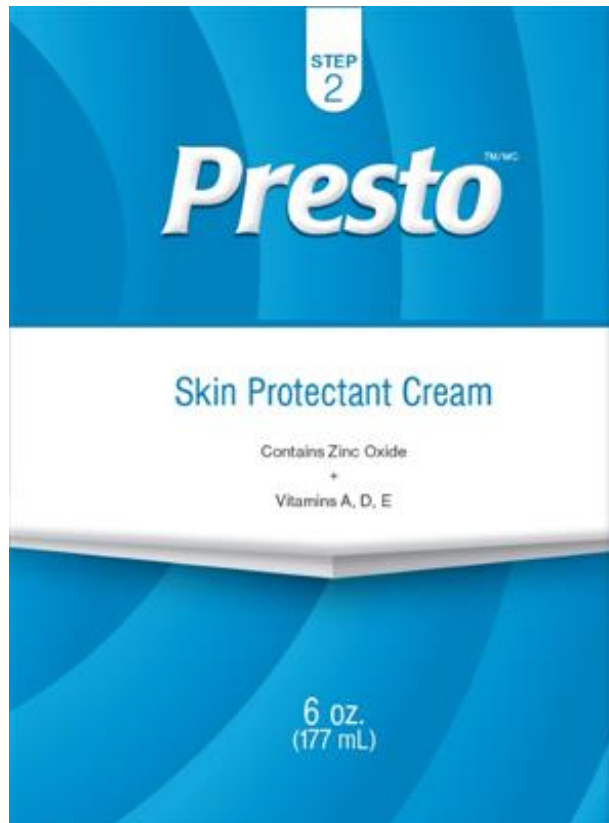
Eau Claire, WI 54703

1-877-202-4652

questions@prestoabsorbent.com

© 2017 Drylock Technologies Ltd.

Made in USA with domestic and imported materials.



NDC 53113-162-06

Drug Facts	
Active ingredient Zinc Oxide 5.0%	Purpose Skin Protectant
Uses • Helps treat and prevent diaper rash. • Protects chafed skin associated with diaper rash and helps protect hemorrhoids.	
Warnings For external use only. When using this product avoid contact with eyes. Stop use and ask a doctor if: • Rash becomes worse. • 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 affected area, and allow to dry. Apply cream liberally as often as necessary, with each change, especially if bedtime or anytime when exposure to wet diapers may be prolonged.	
Ingredients Purified Water, cyclotrisiloxane, tripropyl palmitate, Dicyclohexyl dimethyl siloxane, Cyclopentasiloxane, Polypropylene-4 hydroxyethyl acrylate, Cetyl PEG/PPG-10/1 Dimethicone, Hexyl Laurate, Dimethicone, Tocopherol (Vitamin E), Zinc Magnesium Oxide, Retinyl palmitate (Vitamin A), Cholecalciferol (Vitamin D ₃), Benzoin, Hydrogenated Castor Oil, Sodium Chloride, SMDM Hydrolysis.	

CAUTION: For external use only. Discontinue use if irritation occurs.

Distributed by:
Drylock Technologies Ltd.
3921 North Hastings Way
Eau Claire, WI 54703
1-877-202-4652
questions@prestoabsorbent.com

© 2017 Drylock Technologies Ltd.

Made in USA with domestic and imported materials.

ASC00000



PRESTO

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-162
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 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
APIS CERANA WORKER SECRETION (UNII: PRG8653U8K)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	

CORN OIL (UNII: 8470G57WFM)
CYCLOMETHICONE 4 (UNII: CZ227117JE)
CYCLOMETHICONE 5 (UNII: 0TH5PC10R)
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)
DIMETHICONE (UNII: 92RU3N3Y1O)
DMDM HYDANTOIN (UNII: BYR0546TOW)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
GLYCERIN (UNII: PDC6A3C0OX)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TOCOPHEROL (UNII: R0ZB2556P8)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
WATER (UNII: 059QF0K00R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-162-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/01/2017	

Labeler - GADAL Laboratories, Inc (841305639)

Establishment

Name	Address	ID/FEI	Business Operations
GADAL Laboratories, Inc		841305639	MANUFACTURE(53113-162)