

BUDPAK DIAPER RASH- zinc oxide cream

Budpak 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.

Budpak Diaper Rash Cream

Active Ingredient

Zinc Oxide 13%

Purpose

Skin Protectant

Uses

Helps treat and prevent diaper rash. Protects chafed skin due to diaper rash. 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 in few days.

Keep out of reach of children.

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

Directions

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

Other Information

Store at 20° to 25°C (68° to 77°F).

Inactive Ingredients

Water, Mineral Oil, Petrolatum, Beeswax, Dimethicone, Sorbitan Sesquioleate, Microcrystalline Wax, PEG-30 Dipolyhydroxystearate, Magnesium Sulfate, Phenoxyethanol, Methylparaben, Fragrance, Potassium Hydroxide, Propylparaben, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice.

PRINCIPAL DISPLAY PANEL

Budpak Diaper Rash Cream

Zinc Oxide 13%

NET WT 1 OZ (28 g)

Budpak®

Fresh Scent
Diaper Rash Cream

Instant relief

Drug Facts

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*This product is not manufactured or distributed by Johnson & Johnson Companies, owner of the registered trademark Desitin®.

Fresh Scent
Diaper Rash Cream
Instant relief

Manufactured in India.
Distributed by Budpak, Inc.
100 North Drive
Ronkonkoma, NY 11779
©2014 Budpak, Inc.



Travel Size
Heals, soothes & prevents further diaper rash
NET WT 1 OZ (28g)
Diaper Rash Cream
Fresh Scent
Instant relief
Zinc Oxide Formula with Aloe
Desitin Rapid Relief
*compare to active ingredient in

Travel Size
Heals, soothes & prevents further diaper rash
Crema Para la Irritación del Pañal
Olor Fresco
Instant relief
Zinc Oxide Formula with Aloe
Desitin Rapid Relief
*compare to ingrediente activo en

Budpak®
Fresh Scent
Diaper Rash Cream
Instant relief
Zinc Oxide Formula with Aloe
Desitin Rapid Relief
*compare to active ingredient in

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BUDPAK DIAPER RASH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27293-028
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	13 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-028-14	1 in 1 BOX		
1		14 g in 1 TUBE		
2	NDC:27293-028-28	1 in 1 BOX		
2		28 g in 1 TUBE		
3	NDC:27293-028-35	1 in 1 BOX		
3		35 g in 1 TUBE		
4	NDC:27293-028-42	1 in 1 BOX		
4		42 g in 1 TUBE		
5	NDC:27293-028-02	1 in 1 BOX		
5		113 g in 1 TUBE		
6	NDC:27293-028-03	1 in 1 BOX		
6		226 g in 1 TUBE		
7	NDC:27293-028-04	453 g in 1 JAR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part347	02/14/2014	
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Labeler - Budpak Inc. (183224849)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-028)

Revised: 2/2014

Budpak Inc.