PURISTICS BABY ZINC OXIDE DIAPER RASH - zinc oxide cream Scerene Healthcare, 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.

Diaper Rash Cream

Active Ingredient

Zinc oxide 15.0%

Purpose

Diaper rash cream

Uses

- helps treat and prevent diaper rash
- protects chafed skin 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 in 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, 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

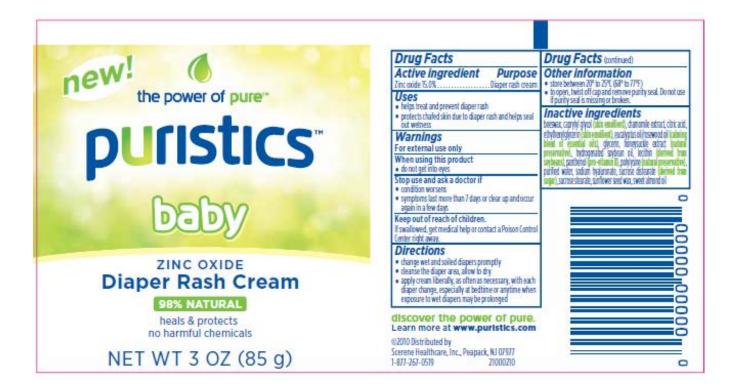
- store between 20° to 25°C (68° to 77°F)
- to open, twist off cap and remove purity seal. Do not use if purity seal is missing or broken.

Inactive Ingredients

beeswax, caprylyl glycol (skin emollient), chamomile extract, citric acid, ethylhexylglycerin (skin emollient), eucalyptus oil/rosewood oil (calming blend of essential oils), glycerin, honeysuckle extract (natural preservative), hydrogenated soybean oil, lecithin (derived from soybeans), panthenol

(pro-vitamin B), polylysine **(natural preservative)**, purified water, sodium hyaluronate, sucrose distearate **(derived from sugar)**, sucrose stearate, sunflower seed wax, sweet almond oil

Principal Display Panel



new!

the power of pure $^{\text{TM}}\,$

puristics $^{\text{TM}}$

baby

ZINC OXIDE

Diaper Rash Cream

98% NATURAL

heals & protects no harmful chemicals

NET WT 3 OZ (85 g)

discover the power of pure.
Learn more at **www.puristics.com**

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PURISTICS BABY ZINC OXIDE DIAPER RASH

zinc oxide cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:76026-200 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	15 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
Yellow Wax (UNII: 2ZA36H0S2V)		
Caprylyl Glycol (UNII: 00 YIU5438 U)		
Chamomile (UNII: FGL3685T2X)		
Citric Acid Monohydrate (UNII: 2968PHW8QP)		
Ethylhexylglycerin (UNII: 147D247K3P)		
Eucalyptus Oil (UNII: 2R04ONI662)		
Rosewood Oil (UNII: F2522O5L7B)		
Glycerin (UNII: PDC6A3C0OX)		
Lonicera Caprifolium Flower (UNII: 5N1WD9784U)		
Hydrogenated Soybean Oil (UNII: A2M91M918C)		
Lecithin, Soybean (UNII: 1DI56QDM62)		
Panthenol (UNII: WV9CM0O67Z)		
Water (UNII: 059QF0KO0R)		
Hyaluronate Sodium (UNII: YSE9PPT4TH)		
Sucrose Stearate (UNII: 274KW0O50M)		
Almond Oil (UNII: 66YXD4DKO9)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:76026-200-30	85 g in 1 TUBE		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part347	12/20/2010			

Labeler - Scerene Healthcare, Inc. (832688209)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bio Zone Laboratories, Inc		555564293	MANUFACTURE	

Revised: 2/2011 Scerene Healthcare, Inc.