

**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.*

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**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**

Drug Facts		Drug Facts (continued)	
<b>Active ingredient</b>	<b>Purpose</b>	<b>Other information</b>	
Zinc oxide 15.0%	Diaper rash cream	<ul style="list-style-type: none"> <li>store between 20° to 25°C (68° to 77°F)</li> <li>to open, twist off cap and remove purity seal. Do not use if purity seal is missing or broken.</li> </ul>	
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**discover the power of pure.**  
Learn more at [www.puristics.com](http://www.puristics.com)

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1-877-267-0519 21000210

**new!**

**the power of pure™**

**puristics™**

**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](http://www.puristics.com)

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**PURISTICS BABY ZINC OXIDE DIAPER RASH**

zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76026-200
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	15 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
Yellow Wax (UNII: 2ZA36H0S2V)	
Caprylyl Glycol (UNII: 00YIU5438U)	
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

