

**BABY DIAPER- zinc oxide cream**  
**TELLURIAN**

*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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ACTIVE INGREDIENTS

ZINC OXIDE, 10%

PURPOSE

SKIN PROTECTANT

USE

- HELPS TREAT AND PREVENT DIAPER RASH.
- PROTECTS CHAPPED SKIN DUE TO DIAPER RASH AND HELPS PROTECT FROM WETNESS.

WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT DO NOT GET INTO EYES.

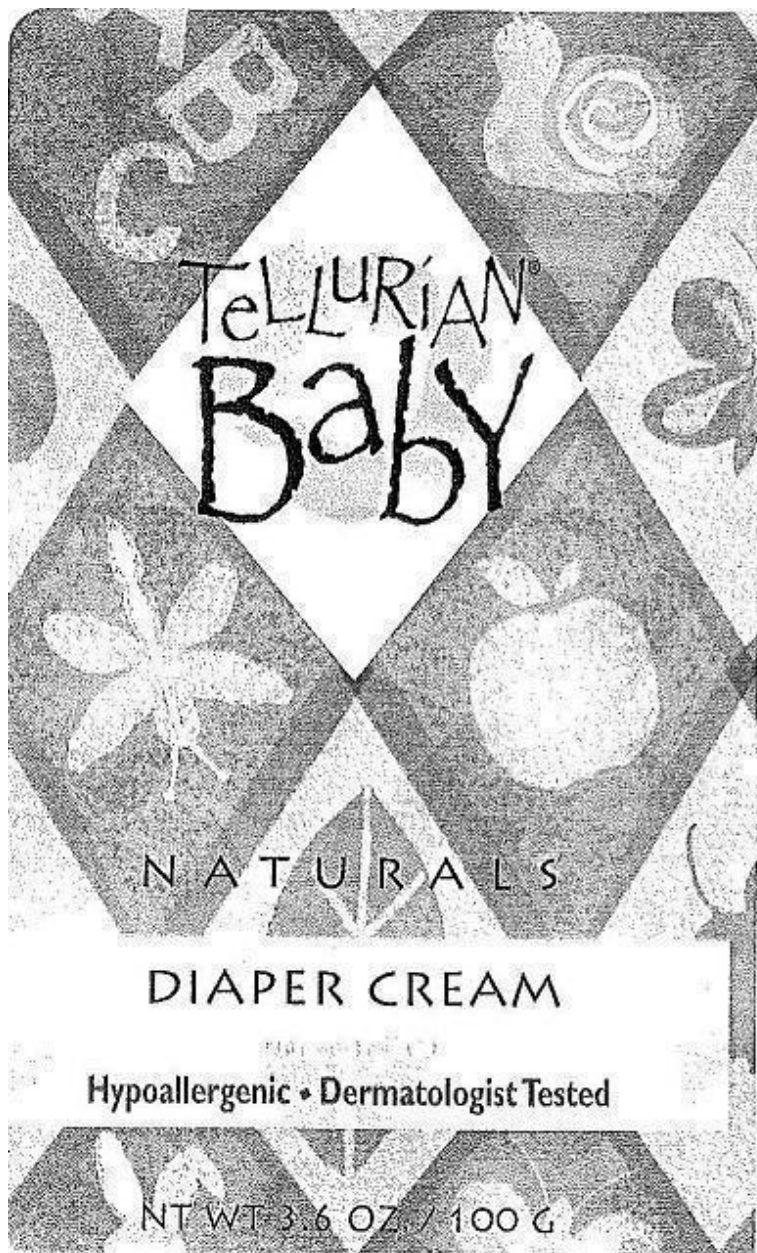
STOP USE AND ASK A DOCTOR IF CONDITION WORSENS OR DOES NOT IMPROVE AFTER 7 DAYS.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, SEEK MEDICAL HELP OR CALL POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

- CHANGE WET AND SOILED DIAPER IMMEDIATELY
- CLEANSE THE DIAPER AREA AND ALLOW SKIN TO DRY.
- APPLY OINTMENT LIBERALLY AND AS OFTEN AS NECESSARY WITH EACH DIAPER CHANGE, ESPECIALLY WHEN EXPOSED TO WET DIAPERS FOR A PROLONGED PERIOD OF TIME, SUCH AS BEDTIME.

Inactive Ingredients: Water, Ethylhexyl Palmitate, Ricinus Communis (Castor) Seed Oil, Polyglycerin-6 Polyricinoleate, Polyglyceryl-10 Hexaoleate, Glycerin, Dimethicone, Sodium PCA, Ceramide 2, Ceramide 3, Ceramide 6lf, Aloe Barbadensis Leaf Juice, Hyaluronic Acid, Macadamia Ternifolia Seed Oil, Vegetable Oil, Camellia Saliva Seed Oil, Phytostearyl Canola Glycerides, Chamomilla Recutita (Matricaria) Extract, Panthenol (Vitamin B5), Tocopheryl Linoleate, Hydrogenated Coco-Glycerides, Myristyl Myristate, Sorbitan Laurate, Sodium Chloride, Zinc Sulfate, Lonicera Caprifolium (Honeysuckle) Flower Extract, Sodium Benzoate, Potassium Sorbate.



**Drug Facts**

Active Ingredients	Purpose
Zinc Oxide, 10%	Skin Protectant

**Use**

- Helps treat and prevent diaper rash.
- Protects chapped skin due to diaper rash and helps protect from wetness.

**Warnings**

For external use only

When using this product do not get into eyes.

Stop use and ask a doctor if condition worsens or does not improve after 7 days.

Keep out of reach of children. If swallowed, seek medical help or call Poison Control Center immediately.

**Directions**

- Change wet and soiled diaper immediately.
- Cleanse the diaper area and allow skin to dry.
- Apply ointment liberally and as often as necessary with each diaper change, especially when exposed to wet diapers for a prolonged period of time, such as at bedtime.

**Inactive Ingredients:** Water, Ethylhexyl Palmitate, Ricinus Communis (Castor) Seed Oil, Polyglycerin-6 Polyricinoleate, Polyglyceryl-10 Hexaoleate, Glycerin, Dimethicone, Sodium PCA, Ceramide 2, Ceramide 3, Ceramide 6II, Aloe Barbadensis Leaf Juice, Hyaluronic Acid, Macadamia Ternifolia Seed Oil, Vegetable Oil, Camelina Sativa Seed Oil, Phytosteryl Canola Glycerides, Chamomilla Recutita (Matricaria) Extract, Panthenol (Vitamin B5), Tocopheryl Linoleate, Hydrogenated Coco-Glycerides, Myristyl Myristate, Sorbitan Laurate, Sodium Chloride, Zinc Sulfate, Lonicera Caprifolium (Honeysuckle) Flower Extract, Sodium Benzoate, Potassium Sorbate.

TELLURIAN  
NEWBURY PARK, CA 91320  
1.888.532.1607  
www.tellurianbaby.com



BABY DIAPER			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42643-101
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	10 g in 10 g
Inactive Ingredients			
Ingredient Name			Strength

<b>WATER</b> (UNII: 059QF0KO0R)
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)
<b>POLYGLYCERIN-6</b> (UNII: M51422LRAM)
<b>POLYGLYCERYL-10 HEXAOLEATE</b> (UNII: 8S25IPV09I)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)
<b>CERAMIDE 3</b> (UNII: 4370DF050B)
<b>CERAMIDE 6 II</b> (UNII: F1X8L2B00J)
<b>CERAMIDE 2</b> (UNII: C04977SRJ5)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>HYALURONIC ACID</b> (UNII: S270N0TRQY)
<b>MACADAMIA OIL</b> (UNII: 515610SU8C)
<b>CORN OIL</b> (UNII: 8470G57WFM)
<b>CANOLA OIL</b> (UNII: 331KBJ17RK)
<b>MATRICARIA CHAMOMILLA WHOLE</b> (UNII: 2Z4LRR776S)
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>Co-co-Glycerides</b> (UNII: ISE9I7DNUG)
<b>MYRISTYL MYRISTATE</b> (UNII: 4042ZC00DY)
<b>SORBITAN MONOLAURATE</b> (UNII: 6W9PS8B71J)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>ZINC SULFATE ANHYDROUS</b> (UNII: 0J6Z13X3WO)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>LONICERA CAPRIFOLIUM FLOWER</b> (UNII: 5N1WD9784U)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42643-101-14	100 g in 1 TUBE		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	01/01/2013	

**Labeler** - TELLURIAN (054233646)