

## **EARTH BABY DIAPER RASH CREAM- zinc oxide cream**

**Earth Baby, 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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### **Earth Baby Diaper Rash Cream**

#### **Active Ingredient**

Zinc Oxide 40%

Skin Protectant

#### **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 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 diaper promptly.

Clean diaper area, allow to dry

Apply a generous amount of cream with each diaper change and before bedtime.

#### **Other information**

Store at 20° - 25°C (68° to 77°F)

#### **Inactive ingredients:**

Avena Sativa (Oat) Kernel Protein, Aloe Barbadensis Leaf Juice\*, Aqua/Water, Beeswax, Canola Oil, Carthamus Tinctorius (Safflower) Oleosomes\*, Caryodendron Orinocense (Kahai) Seed Oil, Cucurbita Pepo (Pumpkin) Extract, Glycerin, Lavandula Intermedia (Lavender) Flower/Leaf/Stem Extract\*, Locinera Japonica (Honeysuckle) Flower Extract, Lonicera Caprifolium (Honeysuckle) Extract, Parfum/Natural Fragrance, Silica, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hyaluronate, Tocopheryl Acetate (Vitamin E), Zea Mays (Corn) Starch.

Helps protect against diaper rash and irritation.

### Drug Facts

Active Ingredient	Purpose
Zinc Oxide 40%	Skin Protectant

#### Uses

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earthbaby®

Formulated Safe + Friendly™ in California  
EARTH BABY, INC.  
Walnut, CA 91789  
Made in the USA  
www.earthbabystore.com

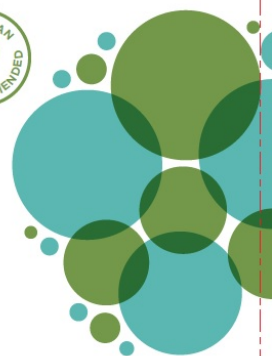
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## DIAPER RASH CREAM +

organic goodness from mother earth®

non-toxic, hypoallergenic  
certified organic ingredients\*  
OleoSphere® technology



Net Wt. 1.7 OZ/50g e

earthbaby®

### DIAPER RASH CREAM +

Beneficially enriched with oat protein and kahai oil to help soothe, calm and heal.

Earth Baby® represents the leading edge in efficacy and safety, combining certified organic ingredients with thoughtfully crafted formulation and award-winning OleoSphere® technology to deliver healthy benefits to baby.  
organic goodness from mother earth®

- Certified Organic Ingredients\*
- Natural Ingredients
- Paraben Free
- Artificial Color Free
- Formaldehyde Free, Sulfate Free
- BSE Free, No Animal Testing

Earth Baby, Organic Goodness from Mother Earth, and Formulated Safe + Friendly are registered trademarks.

## EARTH BABY DIAPER RASH CREAM

zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62588-904
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
CARTHAMUS TINCTORIUS (SAFFLOWER) OLEOSOMES (UNII: 9S60Q72309)	
CARYODENDRON ORINOCENSE WHOLE (UNII: J2T2D81BHU)	
CUCURBITA PEPO WHOLE (UNII: 48V44WX64I)	
GLYCERIN (UNII: PDC6A3C0OX)	
LAVANDULA X INTERMEDIA WHOLE (UNII: 9Q3NSN290F)	

<b>LonicerA caprifolium whole</b> (UNII: 4F67A99YTF)	
<b>OAT kernel oil</b> (UNII: 3UVP41R77R)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>LonicerA japonica flower</b> (UNII: 4465L2WS4Y)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CANOLA OIL</b> (UNII: 331KBJ17RK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62588-904-02	1 in 1 BOX	02/01/2019	12/31/2022
1		50 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/01/2019	12/31/2024

**Labeler** - Earth Baby, Inc (079298651)

Revised: 3/2021

Earth Baby, Inc