

DIAPER RASH CREAM- zinc oxide cream

giggle

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.

giggle diaper rash cream for early 2016

Active Ingredients

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Zinc Oxide: 19%

Purpose

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Skin Protectant

Uses

- Helps treat and prevent diaper rash
- Protects chafed skin associated with diaper rash
- Helps protect against wetness

Warnings

For external use only.

When using this product * avoid contact with eyes.

Stop use and ask a doctor if * condition worsens * symptoms last more than 7 days or clear up and return 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 wet or soiled diaper promptly. * Cleanse the diaper area and allow to dry. * Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or anytime exposure to wet diapers may be prolonged.

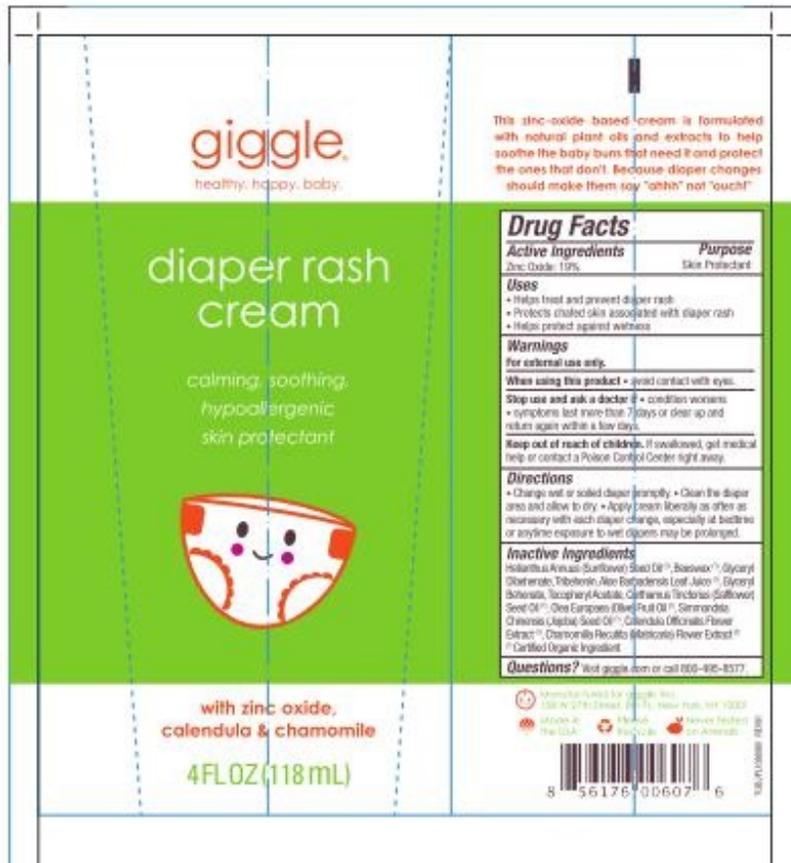
Inactive Ingredients

Helianthus Annuus (Sunflower) Seed Oil ⁽¹⁾, Beeswax ⁽¹⁾, Glyceryl Dibehenate, Tribehenin, Aloe Barbadensis Leaf Juice ⁽¹⁾, Glyceryl Behenate, Tocopheryl Acetate, Carthamus Tinctorius (Safflower) Seed Oil ⁽¹⁾, Olea Europae (Olive) Fruite Oil ⁽¹⁾, Simmondsia Chinensis (Jojoba) Seed Oil ⁽¹⁾, Calendula Officialis Flower Extract ⁽¹⁾, Chamomilla Recutita (Matricaria) Flower Extract ⁽¹⁾⁽¹⁾
Certified Organic Ingredient

Questions?

Questions? Visit giggle.com or call 800-495-8577

Package label principal display panel



DIAPER RASH CREAM

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70306-1851
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
JOJOBA OIL (UNII: 724GKU717M)	
GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
CHAMOMILE (UNII: FGL3685T2X)	

Product Characteristics

Color	white (Off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70306-1851-4	118 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/01/2016	

Labeler - giggle (194045402)

Revised: 2/2016

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