

ZINC OXIDE 40%- diaper rash skin cream BRANDS INTERNATIONAL

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.

Zinc Oxide 40% Diaper Rash Cream

Active Ingredient

Zinc oxide 40%

Purpose

Skin Protectant

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 within a few days

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- change wet and soiled diapers promptly
- cleanse the diaper area
- allow to dry
- apply paste liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

Other Information

- See box for more details

Inactive Ingredients

Sunflower oil, Castor Oil, Sunflower seed wax, polyhydroxystearic acid, shea butter, coconut oil, theobroma cacao seed butter, calophyllum seed oil, tocopherol, zea mays corn starch

Questions and comments?

1-888-880-6888

Label



hello bello

Zinc Oxide
Skin Protectant

**Diaper Rash
Cream**

WORRY-FREE CLEAN STUFF

Created Without

- × Synthetic Fragrance
- × Parabens × Lanolin
- × Mineral Oil

See organic ingredients on back ▶

NET WT. 4.0 fl. oz. (118 ml)e

"Cute as a baby's bottom" loses a little cuteness when the first signs of redness show up. So when it does, whip out this carefully crafted cream and unleash the power of non-nano zinc oxide and skin-supportive ingredients like Tamanu and Coconut Oils.

ACTIVE INGREDIENT
Zinc Oxide – 40%
Purpose
Skin Protectant
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 or 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 wet and soiled diapers promptly. Cleanse the diaper area and allow to dry · Apply cream liberally as often as necessary, with each diaper change, and especially at bedtime or anytime when exposure to wet diapers may be prolonged
Other information
Do not use if quality seal is broken · Do not store above 40°C (104°F)
Inactive Ingredients
Helianthus Annuus (Sunflower) Seed Oil*, Ricinus Communis Seed (Castor) Oil*, Helianthus Annuus (Sunflower) Seed Wax*, Polyhydroxystearic Acid, Butyrospermum Parkii (Shea) Butter*, Cocos Nucifera (Coconut) Oil*, Theobroma Cacao (Cocoa) Seed Butter*, Calophyllum Tacamahaca Seed Oil*, Tocopherol, Zea Mays Corn Starch* – *Organic



VEGAN



OTHER/
MDPE



Questions? (888) 880-6888

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ZINC OXIDE 40%

diaper rash skin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50157-477
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 mL

Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CALOPHYLLUM TACAMAHACA SEED OIL (UNII: 05G85L61OE)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CASTOR OIL (UNII: D5340Y2I9G)	
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-477-18	118 mL in 1 TUBE; Type 0: Not a Combination Product	09/20/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	09/20/2022	

Labeler - BRANDS INTERNATIONAL (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
BRANDS INTERNATIONAL		243748238	manufacture(50157-477)