

ZINC OXIDE- zinc oxide cream
Unconditional Love d/b/a Hello Bello

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.

DRUG FACTS

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

Other information

Do not use if quality seal is broken

- Do not store above 104°F/40°C

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

Helianthus Annuus (Sunflower) Seed Oil, Ricinus Communis (Castor) Seed Oil*, Hydrogenated Palm Oil**, Theobroma Cacao (Cocoa) Seed Butter**, Cetyl Palmitate**, Butyrospermum Parkii (Shea) Butter, Cocos Nucifera (Coconut) Oil, Calophyllum Inophyllum Seed Oil, Tocopherol, Zea Mays (Corn) Starch*

*Organic **RSPO Certified

Principal Display Panel – 118 mL Carton Label

Skin Protectant

**hello
bello™**

*Made with sunflower seed,
coconut, and tamanu oils*

*Soothing Relief
Zinc Oxide Treatment*

**Diaper Rash
Cream**

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

- **Hypoallergenic**
- **Non-Nano Zinc Oxide**
- **Pediatrician Tested**

ZINC OXIDE

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73418-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	480 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
Sunflower Oil (UNII: 3W1JG795YI)	
Castor Oil (UNII: D5340Y2I9G)	
Hydrogenated Palm Oil (UNII: 257THB963H)	
Cocoa butter (UNII: 512OYT1CRR)	
Cetyl Palmitate (UNII: 5ZA2S6B08X)	
Shea Butter (UNII: K49155WL9Y)	
Coconut Oil (UNII: Q9L0O73W7L)	
Tamanu oil (UNII: JT3LVK84A1)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Starch, Corn (UNII: O8232NY3SJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73418-010-01	1 in 1 BOX	02/01/2019	
1		118 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:73418-010-02	1 in 1 BOX	02/01/2019	
2		236 mL 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	

Labeler - Unconditional Love d/b/a Hello Bello (081135707)

Establishment

Name	Address	ID/FEI	Business Operations
Unconditional Love		081135707	MANUFACTURE(73418-010)

Revised: 1/2021

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