

DIAPER RASH CREAM- zinc oxide lotion
EllaOla Brands 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.

Active Ingredient

Zinc Oxide 14%

Warnings

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.

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Purpose

Skin Protectant

Warnings

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Inactive Ingredients

Beeswax, Butyrospermum Parkii (Shea) Butter, Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil, Copernicia Cerifera (Carnauba) Wax, Helianthus Annuus (Sunflower) Seed Oil, Laminaria Ochroleuca Extract, Polyglyceryl-2 Dipolyhydroxystearate, Ricinus Communis (Castor) Seed Oil

Uses

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash
- Helps seal out wellness

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

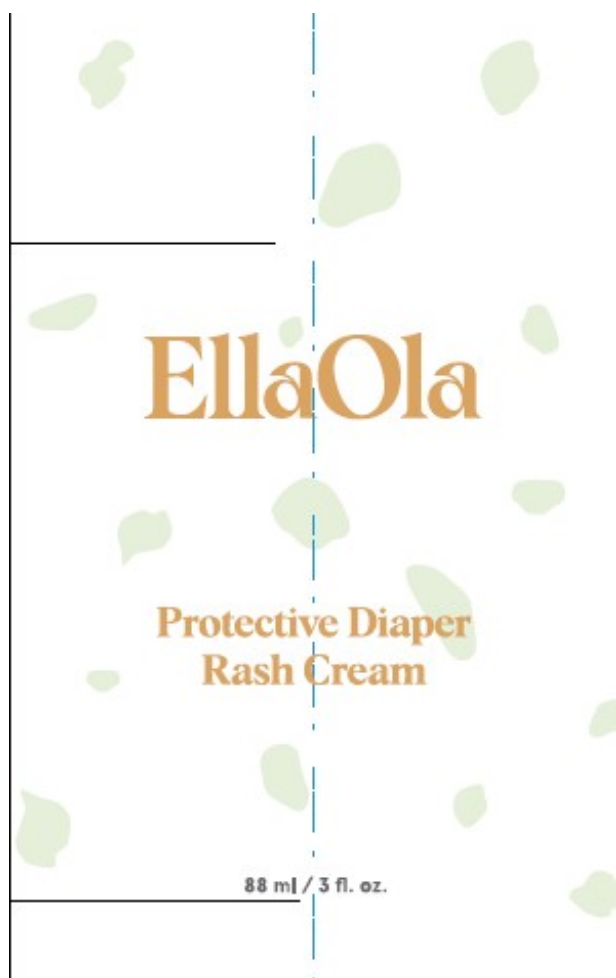
Apply cream liberally as often as necessary with each diaper change, especially at bedtime or anytime when exposed to wet diapers may be prolonged.

Other information

Store at room temperature and protect this product from direct sunlight.

Directions

Apply cream liberally as often as necessary with each diaper change, especially at bedtime or anytime when exposure to wet diapers maybe be prolonged.



EllaOla Diaper Cream Tube 88mL NDC: 82057-579-01

EllaOla

Protective
Diaper
Rash Cream

88 ml / 3 fl. oz.

EllaOla Diaper Cream Carton NDC: 82057-579-02

DIAPER RASH CREAM

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82057-579
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 g in 88 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CASTOR OIL (UNII: D5340Y2I9G)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82057-579-02	1 in 1 CARTON	09/30/2021	
1	NDC:82057-579-01	88 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	09/30/2021	

Labeler - EllaOla Brands Inc. (118147901)**Registrant** - EllaOla Brands Inc. (118147901)

Revised: 6/2021

EllaOla Brands Inc.