

DIAPER RASH CREAM 2.5OZ- zinc oxide cream
Rejoice International Corp.

DIAPER RASH CREAM 2.5OZ

Active ingredient

Zinc Oxide 40%

Purpose

Skin protectant

Use

- helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness.

Warnings

Warnings: For external use only.

When using this product

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.

Do not use

Do not use if tube seal under cap is broken or missing

Directions

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

Other information

- store at 68° to 77°F (20° to 25°C)

- do not use if tube seal under cap is broken or missing

Inactive ingredients

Petrolatum, Mineral Oil, Lanolin, Isopropyl Myristate, Beeswax, Tocopheryl Acetate, Cod Liver Oil, Aloe Barbadosensis Leaf Juice

label



playtex
baby™

40% Zinc Oxide Diaper Rash Cream

Quick, Effective Relief

Maximum Strength

NET WT. 2.5 OZ (71 g)



Dermatologist
Tested



Hypo-
Allergenic

Drug Facts

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Drug Facts (continued)

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Designed in the USA. Made in India.
Distributed by: Rejoice International Corp.
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DIAPER RASH CREAM 2.5OZ

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-165
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
COD LIVER OIL (UNII: BBL281NWFG)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
LANOLIN (UNII: 7EV65EAW6H)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-165-01	1 in 1 BOX	03/07/2024	
1		71 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 Drug	M016	03/07/2024	

Labeler - Rejoice International Corp. (078741245)

Establishment

Name	Address	ID/FEI	Business Operations
Gandhar Oil Refinery (India) Ltd.		725188184	manufacture(57337-165)

Establishment

Name	Address	ID/FEI	Business Operations
Astonea Labs Private Limited		878533295	manufacture(57337-165)

Establishment

Name	Address	ID/FEI	Business Operations
VASA COSMETICS PRIVATE LIMITED		955446947	manufacture(57337-165)

Revised: 10/2024

Rejoice International Corp.