

DIAPER RASH CREAM 40% ZINC- zinc oxide cream
ASTONEA LABS PRIVATE LIMITED

DIAPER RASH CREAM 2OZ

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

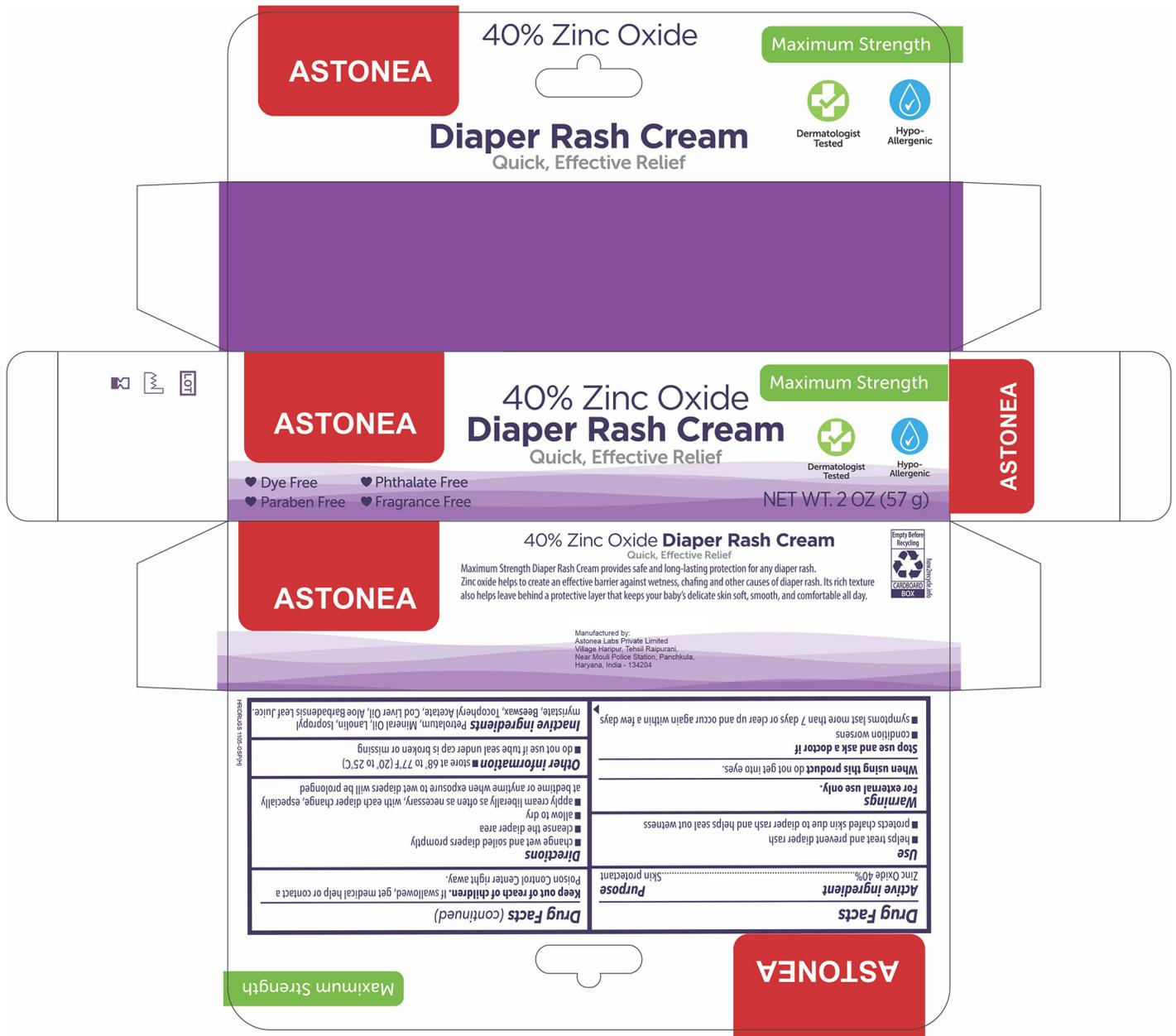
- store at 68° to 77°F (20° to 25°C)

- 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 Barbadensis Leaf Juice

label



DIAPER RASH CREAM 40% ZINC

zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:77338-164

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)	
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
LANOLIN (UNII: 7EV65EAW6H)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-164-01	1 in 1 BOX	03/06/2024	
1		57 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:77338-164-02	71 g in 1 TUBE; Type 0: Not a Combination Product	03/06/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	03/06/2024	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Establishment

Name	Address	ID/FEI	Business Operations
Astonea Labs Private Limited		878533295	manufacture(77338-164)

Revised: 4/2024

ASTONEA LABS PRIVATE LIMITED