

ASTONEA XERO- skin protectant ointment
ASTONEA LABS PRIVATE LIMITED

ASTONEA XERO

Active Ingredients:

Zinc Oxide 15%

Dimethicone 1%

Purpose:

Skin Protectant

Uses:

- Helps treat and prevent diaper rash.
- Protects minor skin irritation associated with diaper rash and helps seal out wetness.

Warnings:

- **For external use only,**
- **Avoid contact with eyes,** In case of contact, flush thoroughly with water.

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.

In case of accidental ingestion contact a physician or 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, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other Information:

- Store between 15-30 °C

Inactive Ingredients:

Aloe vera Extract, Cholecalciferol, Eugenia Caryophyllus Flower Oil, Lanolin, Light Liquid Paraffin, Petrolatum, Retinyl Palmitate, Tocopheryl Acetate

Label Principal Display Panel

Drug Facts	
Active Ingredients	Purpose
Zinc Oxide 15% w/w	Skin Protectant
Dimethicone 1% w/w	Skin protectant
Uses ■ Helps treat and prevent diaper rash. ■ Protects minor skin irritation associated with diaper rash and help seal out wetness.	
Warnings ■ For external use only	
<p>Avoid contact with eyes. In case of contact, flush thoroughly with water. Stop use and ask a doctor if</p> <p>■ Condition worsens ■ Symptoms last more than 7 days or clear up and occur again within a few days.</p> <p>Keep out of reach of children. In case of accidental ingestion contact a physician or Poison Control Center right away.</p>	
Directions	
<p>■ Change wet and soiled diaper promptly, cleanse the diaper area and allow to dry. ■ Apply cream liberally as often as necessary with each diaper change, especially at bedtime or anytime when exposure to wet diaper may be prolonged.</p>	
Other Information	
■ Store between 15°-30°C (59°-86°F)	
Inactive Ingredients	
Aloe vera Extract, Cholecalciferol, Eugenia Caryophyllus Flower Oil, Lanolin, Light Liquid Paraffin, Petrolatum, Retinyl Palmitate, Tocopheryl Acetate	

Patient Name:
Room #:

ASTONEA

Medicated Barrier Cream

with Zinc Oxide
and Dimethicone



Manufactured by:
Astonea Labs Private Limited
Village Haripur, Tehsil Raipurani,
Near Mouli Police Station,
Panchkula, Haryana,
India - 134204

HR/DRUGS 1105-05P(H)

ASTONEA XERO
skin protectant ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PETROLATUM (UNII: 4T6H12BN9U)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CLOVE LEAF OIL (UNII: VCA5491KVF)	
LANOLIN (UNII: 7EV65EAW6H)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-022-23	113 g in 1 TUBE; Type 0: Not a Combination Product	08/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	08/18/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)