

ASTONEA XERO- skin protectant ointment
ASTONEA LABS PRIVATE LIMITED

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.

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	
Avoid contact with eyes. In case of contact, flush thoroughly with water. 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. In case of accidental ingestion contact a physician or Poison Control Center right away.	
Directions ■ 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.	
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 final	part347	08/18/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 12/2022

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