

ASTONEA SKIN PROTECTANT- zinc oxide ointment
ASTONEA LABS PRIVATE LIMITED

Astonea skin protectant 1.8% ZNO

Drug Facts

Active ingredient

Zinc Oxide (1.8% w/w)

Purpose

Skin Protectant

Uses:

- Helps treat and prevent diaper rash, incontinence or exposure to feces and urine
- Protects Skin against irritation due to such rash and
- Helps protect skin from exposure to wetness

Warnings:

For external use only

When using this product

- Avoid contact with eyes
- If eye contact occurs, flush with water

Stop use and ask a doctor if:

- Condition worsens or does not improve within seven days

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away

Directions:

- Change wet or soiled diapers promptly
- Clean diaper area with a mild cleanser, paying special attention to the perinium, buttocks, lower abdomen and inner thighs
- Allow to dry
- Apply to affected area as often as necessary or with each diaper change, especially at bedtime or any time when exposure to soiled diapers may be prolonged

Other information:

- Store at room temperature 15° - 30°C (59° - 86°F)

- Avoid excessive heat

Inactive ingredients:

Aloe Barbadensis Gel, Alpha-Tocopherol(Vitamin E), Cetostearyl Alcohol, Cholecalciferol (Vitamin D), Ethylhexylglycerine, FD&C Yellow No. 5, FD&C Yellow No. 6, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Lanolin, Lavender, Mineral Oil, Paraffin, Phenoxyethanol, Sodium Benzoate, Sodium Laureth-3 Sulfate, stearic acid, Vitamin A Palmitate, Water.

Package Labeling:

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide 1.8% w/w	Skin Protectant
Uses ■ Helps treat and prevent rash associated with diaper rash, incontinence or exposure to feces and urine ■ Protects skin against irritation due to such rash and ■ Helps protect skin from exposure to wetness	
Warnings ■ For external use only	
When using this product ■ Avoid contact with eyes ■ If eye contact occurs, flush 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. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ Change wet or soiled diapers promptly ■ Clean diaper area with a mild cleanser, paying special attention to the perineum, buttocks, lower abdomen and inner thighs ■ Allow area to dry ■ Apply to affected area as often as necessary or with each diaper change, especially at bedtime or any time when exposure to soiled diapers may be prolonged	
Other Information ■ Store at room temperature 15°-30°C (59°-86°F) ■ Avoid excessive heat	
Inactive Ingredients Aloe Barbadensis Gel, Alpha Tocopherol (Vitamin E), Cetostearyl Alcohol, Cholecalciferol (Vitamin D), Ethylhexylglycerin, FD&C Yellow No.5, FD&C Yellow No.6, Glycerin, Glyceryl Mono Stearate, Isopropyl Myristate, Lanolin, Lavender, Mineral Oil, Paraffin, Phenoxyethanol, Sodium Benzoate, Sodium Laureth-3 Sulfate, Stearic Acid, Vitamin A Palmitate, Water	

Patient Name:
Room #:

ASTONEA

**Skin
Protectant**

Specially formulated for
Gentle Skin



ALOE VERA
VITAMINA · VITAMIN D
VITAMINE · ZINC OXIDE

4 Oz. (113g)

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

HR/DRUGS 1105-OSP(H)

ASTONEA SKIN PROTECTANT

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-050-04	113 g in 1 TUBE; Type 0: Not a Combination Product	08/17/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	11/21/2019	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Establishment

Name	Address	ID/FEI	Business Operations
ASTONEA LABS PRIVATE LIMITED		878533295	manufacture(77338-050)

Revised: 6/2024

ASTONEA LABS PRIVATE LIMITED