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 solied 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.

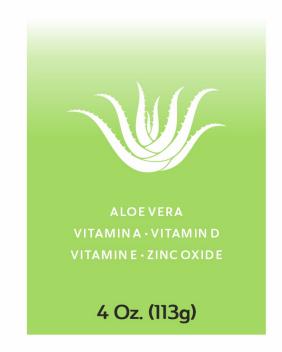
Package Labeling:

Patient Name:

ASTONEA

Skin **Protectant**

Specially formulated for Gentle Skin



Drug Facts

Active Ingredient 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.

■ 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

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)
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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: 2300U9XXE4)	
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: 1900E3H2ZE)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

l	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