

**ASTONEA PERISHIELD- zinc oxide 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.*

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**astonea PeriShield**

***Active Ingredient***

Zinc Oxide 3.8%

***Purpose***

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 or doesn't 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 and 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 anytime when exposure to soiled diapers may be prolonged

## Inactive ingredients

Aloe Barbadensis Gel, Alpha Tocopherol (Vitamin E), Cholecalciferol (Vitamin D), Chloroxylenol, Cetostearyl Alcohol, Corn Oil, Ethylhexylglycerin, FD&C Yellow No. 5, FD&C Yellow No. 6, Fragrance, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Lanolin, Microcrystalline wax, Mineral Oil, Paraffin, Phenoxyethanol, Sodium Borate, Sodium Laureth-3 Sulfate, Stearic Acid, Vitamin A Palmitate, Water

## Package Label

# ASTONEA



## Skin Protectant Ointment

For the Treatment or Prevention of Rash Associated with Diaper Use, Incontinence or Exposure to Feces and Urine

Forms Protective Barrier to Seal out Wetness

Zinc Oxide

Vitamin A, D & E

3.5 OZ. (100 GRAMS)

### Skin Protectant Ointment

#### Drug Facts

| Active ingredient   | Purpose         |
|---------------------|-----------------|
| Zinc Oxide 3.8% 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 or doesn't 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 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 Vera Leaf, Alpha Tocopherol (Vitamin E), Cholecalciferol (Vitamin D), Chloroxylenol, Cetostearyl Alcohol, Corn Oil, Ethylhexylglycerin, FD&C Yellow No. 5, FD&C Yellow No. 6, Fragrance, Glycerin, Glyceryl Monostearate, Isopropyl Myristate, Lanolin, Light Mineral Oil, Microcrystalline Wax, Paraffin, Phenoxyethanol, Sodium Borate, Sodium Laureth-3 Sulfate, Stearic Acid, Vitamin A Palmitate, Water

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

**Made in India**  
HRDRUGS 1105-OSP(H)

## ASTONEA PERISHIELD

zinc oxide ointment

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:77338-802 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 3.8 g in 100 g |

### Inactive Ingredients

| Ingredient Name                             | Strength |
|---|----------|
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M)        |          |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)    |          |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)           |          |
| CHLOROXYLENOL (UNII: 0F32U78V2Q)            |          |
| CHOLECALCIFEROL (UNII: 1C6V77QF41)          |          |
| CORN OIL (UNII: 8470G57WFM)                 |          |
| LANOLIN (UNII: 7EV65EAW6H)                  |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)           |          |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)      |          |
| SODIUM BORATE (UNII: 91MBZ8H3QO)            |          |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)         |          |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)       |          |
| SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0) |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)             |          |
| GLYCERIN (UNII: PDC6A3C0OX)                 |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)      |          |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)     |          |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)      |          |
| MINERAL OIL (UNII: T5L8T28FGP)              |          |
| PARAFFIN (UNII: I9O0E3H2ZE)                 |          |
| WATER (UNII: 059QF0KOOR)                    |          |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)        |          |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:77338-802-04 | 452 g in 1 JAR; Type 0: Not a Combination Product  | 08/09/2022           |                    |
| 2 | NDC:77338-802-00 | 100 g in 1 TUBE; Type 0: Not a Combination Product | 08/09/2022           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347                                  | 08/09/2022           |                    |

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**Labeler** - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 8/2022

ASTONEA LABS PRIVATE LIMITED