

ASTONEA PERISHIELD- zinc oxide ointment
ASTONEA LABS PRIVATE LIMITED

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





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

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 ■ Clean diaper area with a mild cleanser, paying special attention to the perineum, buttocks, lower abdomen and inner thighs
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 ■ 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 Haripur, Tehsil Raipurani,
 Near Mouli Police Station,
 Panchkula, Haryana,
 India - 134204

Made in India
 HRDRUGS 1105-05P(H)

ASTONEA PERISHIELD

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-802
Route of Administration	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: 059QF0K00R)	
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 Drug	M016	08/09/2022	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

