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.

astonea PeriShield

Active Ingredient

7 inc 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.

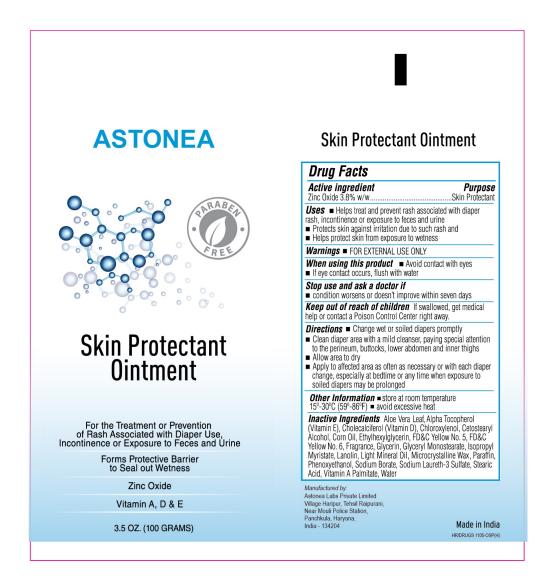
Directions

■ 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 PERISHIELD

zinc oxide ointment

Product Information

	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-802
ı	Route of Administration	TOPICAL		

tive Ingredient/Active Moiety			
Ingredient Name	Basis of Strength Strengt		
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: 2300U9XXE4)		
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: 1900E3H2ZE)		
WATER (UNII: 059QF0KO0R)		
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 In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	08/09/2022		

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 8/2022 ASTONEA LABS PRIVATE LIMITED