

ASTONEA- 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 Zinc oxide 20%

Active Ingredient

Zinc Oxide 20% w/w

Purpose

Skin Protectant

Uses

■ helps treat and prevent diaper rash ■ dries the oozing and weeping of ■ poison ivy
■ poison oak ■ poison sumac

Warnings

For external use only

When using this product

■ do not get into eyes
■ do not use over large areas of the body

Stop use and ask a doctor if

■ the condition worsens ■ symptoms last more than 7 days or clear up and occur again in a few days ■ if you are allergic to any of these ingredients

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

■ for diaper rash ■ change wet and soiled diapers promptly ■ cleanse the diaper area and allow to dry ■ apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged ■ for poison ivy, oak sumac ■ apply ointment liberally as often as needed

Other Information

■ store at 59-86F (15-30C)

Inactive Ingredients

cetostearyl alcohol, cetomacrogol 1000, lanolin, light liquid paraffin, white soft paraffin

Package Label

ASTONEA ZINC OXIDE OINTMENT

ZINC OXIDE 20%

Skin Protectant

NET WT.: 2 OZ. (56.6G)

Drug Facts	Purpose
Active ingredient Zinc Oxide (20%w/w).....Skin Protectant	Uses ■ Helps treat and prevent diaper rash ■ Dries the oozing and weeping of ■ Poison Ivy ■ Poison oak ■ Poison sumac Warnings: For external use only. When using this product ■ Do not get into eyes ■ Do not use over large area of the body Stop use and consult a doctor if ■ Condition worsens ■ Symptoms last more than 7 days or clear up and occur again in a few days ■ If you are allergic to any of the ingredients Do not use on ■ Deep puncture wounds ■ Animal bites ■ Serious burns Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center immediately Directions for Diaper Rash ■ Change wet and soiled diaper promptly ■ Cleanse the diaper area and allow to dry ■ Apply as needed Other Information ■ Store at 15°-30°C (59°-86°F) ■ Avoid excessive heat
Inactive ingredients: Cetomacrogol 1000, Cetostearyl Alcohol, Lanolin, Light Liquid Paraffin, White Soft Paraffin	
ZINC OXIDE OINTMENT ZINC OXIDE 20% Skin Protectant NET WT.: 2 OZ. (56.6G)	

Manufactured by:
Astonea Labs Private Limited
 Village Haripur, Tehsil Haripur,
 Near Mohli Police Station, Panchkula,
 Haryana, India - 154204
 Made in India
 HANSAS 14232479

ASTONEA

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77338-304
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77338-304-03	28.3 g in 1 TUBE; Type 0: Not a Combination Product	05/23/2013	
2	NDC:77338-304-04	56.6 g in 1 TUBE; Type 0: Not a Combination Product	05/23/2013	
3	NDC:77338-304-05	425 g in 1 JAR; Type 0: Not a Combination Product	05/23/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/23/2013	

Labeler - ASTONEA LABS PRIVATE LIMITED (878533295)

Revised: 8/2022

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