

ANCALIMA ZINC OXIDE- zinc oxide ointment
ANCALIMA LIFESCIENCES 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.

Ancalima Zinc oxide 20%

Active Ingredient

Zinc Oxide 20% w/w

Purpose

Diaper Rash Cream

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, light liquid paraffin, white soft paraffin

Package Label




Ancalima

Net Wt.
2 oz (56.68g)

Zinc Oxide Ointment

SKIN PROTECTANT

NDC: 73014-3040-4



Reorder No:
ACM-30404

Drug Facts	<p>Active ingredient Zinc Oxide 20% w/w. Diaper Rash Cream</p> <p>Purpose ■ helps treat and prevent diaper rash ■ dries the oozing and weeping of poison ivy ■ poison oak ■ poison sumac</p> <p>Warnings For external use only</p> <p>When using this product ■ do not get into eyes ■ do not use over large areas of the body</p> <p>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</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away</p> <p>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 any time when exposure to wet diapers may be prolonged ■ for poison ivy, oak, sumac ■ apply ointment liberally as often as needed</p> <p>Other information ■ store at 59°-86°F (15°-30°C) ■ avoid excessive heat</p> <p>Inactive ingredients cetostearyl alcohol, cetomacrogol 1000, light liquid paraffin, white soft paraffin</p>	<p>Reorder No: ACM-30404</p> <p><small>Manufactured by: Ancalima Lifesciences Limited 50th KM Stone, National Highway No.1, Murthal, Sonapat Haryana 131001, Made in India HDKUS7528PH</small></p>
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ANCALIMA ZINC OXIDE

zinc oxide ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73014-3040
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
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHXX)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73014-3040-3	28 g in 1 TUBE; Type 0: Not a Combination Product	04/08/2019	

2	NDC:73014-3040-4	56 g in 1 TUBE; Type 0: Not a Combination Product	04/08/2019	
3	NDC:73014-3040-5	425 g in 1 JAR; Type 0: Not a Combination Product	04/08/2019	
4	NDC:73014-3040-6	453 g in 1 JAR; Type 0: Not a Combination Product	04/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/08/2019	

Labeler - ANCALIMA LIFESCIENCES LIMITED (676760093)

Revised: 1/2021

ANCALIMA LIFESCIENCES LIMITED