

LEADER ZINC OXIDE- zinc oxide ointment
Cardinal Health LLC

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.

Drug Facts

Active Ingredient

Zinc oxide 20%

Purpose

Skin Protectant

Uses

- helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness.
- dries the oozing and weeping of poison ivy, poison oak and poison sumac.

Warnings

For external use only

When using this product, avoid contact with the eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days to clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Directions

- apply liberally as often as necessary

For Diaper Rash

- change wet or soiled diapers promptly
- cleanse the diaper area and allow to dry
- apply ointment liberally, as often as necessary, with each diaper change and especially at bedtime or anytime when exposure to wet diapers may be prolonged

For Poison Ivy, poison oak and poison sumac;

- cleanse the affect area and pat dry
- apply ointment liberally, as often as necessary, using a cotton ball, sterile swab or gauze
- wash hands after use.

Inactive ingredients

mineral oil, petrolatum

Questions or comments ?

Call 1-800-222-1087

Store at room temperature 20 - 25°C (68° - 77°F).

Principal Display Panel – Jar Label

Leader® NDC 70000-0334-1

Zinc Oxide

Ointment USP•

Multi Purpose Skin Protectant

provides soothing relief from poison ivy,
oak and sumac

Treats and prevents diaper rash

Net Wt 1 lb (454 g)

LEADER[®]

NDC 70000-0334-1

Zinc Oxide Ointment, USP

Multi Purpose Skin Protectant

Provides Soothing Relief from Poison Ivy, Oak and Sumac

Treats and Prevents Diaper Rash

100% Money Back Guarantee

NET WT 16 OZ (454 g)

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Other information: Store at controlled room temperature 68°-77° F (20°-25° C)
Inactive ingredients: Mineral Oil, Petrolatum
Questions or Comments?: 1-800-222-1087

REV. 7/18

0 96295 13322 6

100% Money Back Guarantee
Return unused product for a full refund.

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LEADER ZINC OXIDE
zinc oxide ointment

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0334
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)			ZINC OXIDE	200 mg in 1 g
Inactive Ingredients				
Ingredient Name				Strength
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0334-1	454 g in 1 JAR; Type 0: Not a Combination Product	03/29/2019	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part347	03/29/2019	

Labeler - Cardinal Health LLC (097537435)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(70000-0334)