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•

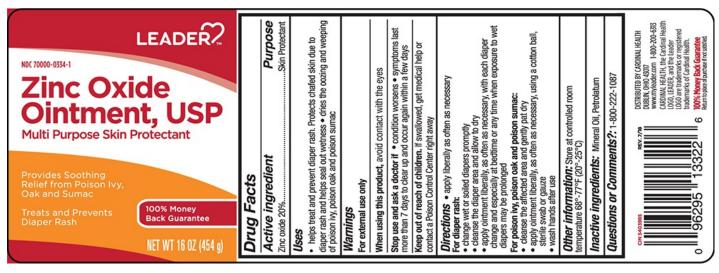
Multi Purpose Skin Protectant

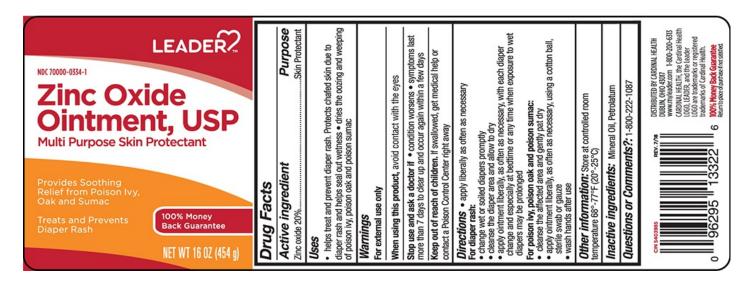
provides soothing relief from poison ivy,

oak and sumac

Treats and prevents diaper rash

Net Wt 1 lb (454 g)





LEADER 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				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	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)	

Revised: 10/2018 Cardinal Health LLC