ZINC OXIDE 20%- zinc oxide ointment
Trifecta Pharmaceuticals USA 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.

Zinc Oxide Ointment 20%

Drug Facts

Active Ingredient

Zinc Oxide 20%

Purpose

Skin Protectant

Uses

- Protects skin
- Protects and releives chafed skin due to diaper rash - helps seal out wetness
- Dries the oozing and weeping of poison ivy, oak and sumac

Keep out of the reach of children

If swallowed, get medical help or contact a Poison Control Center immediately.

Warnings

For External Use Only

- When using this product avoid contact with eyes
- Stop use and ask a doctor if condition worsens or does not improve within 7 days. This may be a sign of a serious condition.

Directions

- Apply ointment liberally as often as necessary
- For the treatment of diaper rash, change wet and soiled diapers promptly
- Cleanse the diaper area and allow to dry
- Apply with each diaper change, especially at bedtime or anytime when exposure to wet diaper may be prolonged

Other Information

- Store at controlled room temperature 15° - 30°C (59° - 86°F)

Inactive Ingredients

Mineral Oil, Petrolatum

Distributed By:

Trifecta Pharmaceuticals USA, LLC.

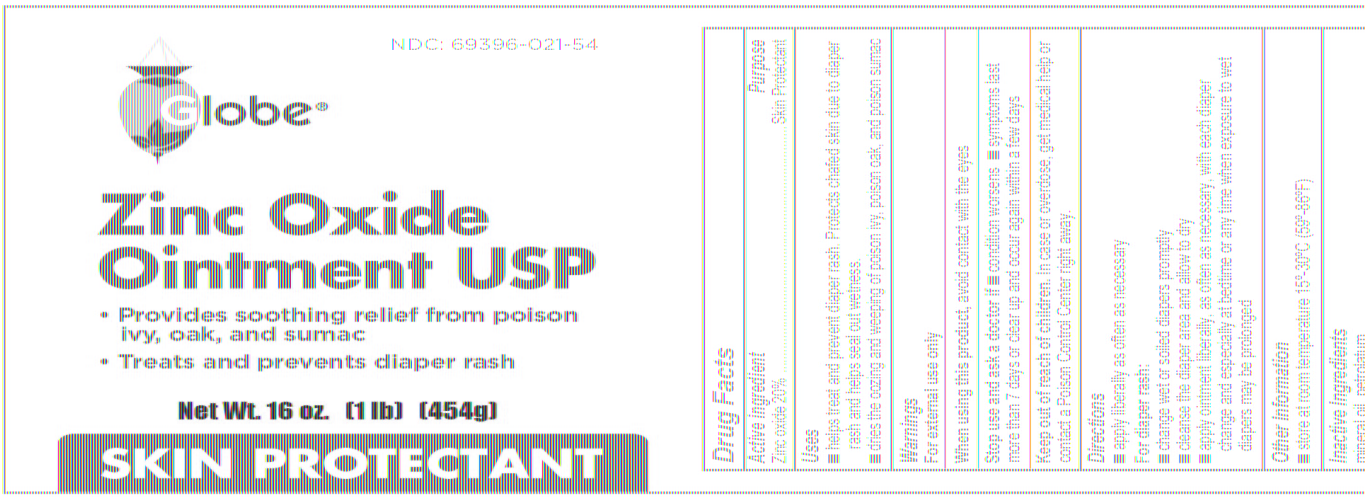
101 NE Third Avenue, Ste. 1500

Ft. Lauderdale, FL. 33301, USA.

Product of PRC

www.trifecta-pharma.com

OUTER LABEL



ZINC OXIDE 20%

zinc oxide ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69396-021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.2 g 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:69396-021-54	1 in 1 JAR	07/01/2019	
1		454 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/01/2019	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 7/2019 Trifecta Pharmaceuticals USA LLC