

**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.*

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**Zinc Oxide Ointment 20%**

**Drug Facts**

**Active Ingredient**

Zinc Oxide 20%

**Purpose**

Skin Protectant

**Uses**

- Protects skin
- Protects and relieves 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.

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Ft. Lauderdale, FL. 33301, USA.

Product of PRC

www.trifecta-pharma.com

OUTER LABEL

NDC: 69396-021-54

**Globe®**

**Zinc Oxide Ointment USP**

- Provides soothing relief from poison ivy, oak, and sumac
- Treats and prevents diaper rash

Net Wt. 16 oz. (1 lb) (454g)

**SKIN PROTECTANT**

<b>Drug Facts</b>	<b>Purpose</b> Zinc oxide 20% Skin Protectant
<b>Uses</b>	<ul style="list-style-type: none"> <li>■ helps treat and prevent diaper rash. Protects chafed skin due to diaper rash and helps seal out wetness.</li> <li>■ dries the oozing and weeping of poison ivy, poison oak, and poison sumac.</li> </ul>
<b>Warnings</b>	<p>For external use only</p> <p>When using this product, avoid contact with the eyes</p> <p>Stop use and ask a doctor if condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>
<b>Directions</b>	<ul style="list-style-type: none"> <li>■ apply liberally as often as necessary</li> </ul> <p>For diaper rash:</p> <ul style="list-style-type: none"> <li>■ change wet or soiled diapers promptly</li> <li>■ cleanse the diaper area and allow to dry</li> <li>■ apply ointment liberally, as often as necessary, with each diaper change and especially at bedtime or any time when exposure to wet diapers may be prolonged</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>■ store at room temperature 15°-30°C (59°-86°F)</li> </ul>
<b>Inactive Ingredients</b>	mineral oil, retinatum

**ZINC OXIDE 20%**

zinc oxide ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-021
<b>Route of Administration</b>	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