

ZINC OXIDE 20%- zinc oxide ointment
Trifecta Pharmaceuticals USA

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 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.

101 NE Third Avenue, Ste. 1500


Ft. Lauderdale, FL. 33301, USA.

Product of PRC

www.trifecta-pharma.com

OUTER LABEL

NDC: 69396-021-54



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

Drug Facts	
Active Ingredient Zinc oxide 20%	Purpose Skin Protectant
Uses <ul style="list-style-type: none"> ■ 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 or clear up and occur again within a few days	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> ■ apply liberally as often as necessary For diaper rash: <ul style="list-style-type: none"> ■ 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 any time when exposure to wet diapers may be prolonged 	
Other Information <ul style="list-style-type: none"> ■ store at room temperature 15°-30°C (59°-86°F) 	
Inactive Ingredients mineral oil, petrolatum	

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 (079424163)

Revised: 4/2023

Trifecta Pharmaceuticals USA