ZINC OXIDE- zinc oxide ointment cream
Gentell, Inc,.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Warnings

For external use only.• Avoid contact with eyes.•

Stop use & ask a doctor if condition worsens or does not improve

within 7 days.• Keep out of reach of children.•

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

Uses

Helps treat & prevent diaper rash.

Protects chafed skin assoicated with diaper rash & helps

protect from wetness. Effective for treating poison ivy,

poison oak & sumac.

Inactive Ingredients

Light Mineral Oil & White Petrolatum

Active Ingredients (In each gram)

Zinc Oxide 20% Skin Protectant

Directions

Gently cleanse affected area and allow to dry before application.

Apply ointment liberally & as often as necessary.

For diaper rash, chage wet and soiled diapers promptly.

Use with each diaper change, especially when exposure to wet

diapers may be prolonged.

Other Information

Lot Number & Expiration Date; see bottom of container.

Store at controlled room temperature (59°F - 86°F).

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ZINC OXIDE

zinc oxide ointment cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61554-234(NDC:71395-715)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.2 kg in 1 kg

Inactive Ingredients	
Ingredient Name	**Strength**
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61554-234-01	28.3 kg in 1 TUBE; Type 0: Not a Combination Product	03/24/2017	
2	NDC:61554-234-00	454 kg in 1 JAR; Type 0: Not a Combination Product	03/24/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/03/2014	

Labeler - Gentell, Inc,. (170967876)

Establishment

Name	Address	ID/FEI	Business Operations
Gentell,Inc.		170967876	repack(61554-234)

Revised: 3/2017 Gentell, Inc,.