## ZINC OXIDE- zinc oxide ointment Galentic Pharma (India) Priva Te Limited

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

Section Text

Active Ingredient Purpose

Zinc Oxide (200mg in each gram) Skin Protectant

# Uses:

- Helps treat and prevent diaper rash.
- Dries the oozing and weeping of;
- poisonivy
- poison oak
- poison sumac

## Warnings:

## For External Use Only

#### When using this product:

• Do not get in eyes.

# Stop use and ask a doctor if:

- conditions worsens
- symptoms last more than 7 days or clear up and occur again in a few days, consult a physician.
- over large areas of the body
- if you are allergic to any of these ingredients

#### Do not use on:

- deep or puncture wounds
- animal bites
- serious burns

# Keep out of reach of children

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions:**

#### For diaper rash:

- change wet and soiled diapers promptly
- cleanse the diaper area and allow to dry

• apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged

## For poison ivy, poison oak, poison sumac:

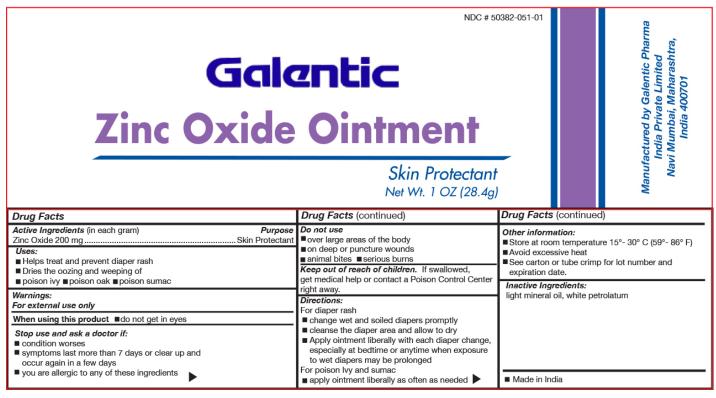
• apply liberally as often as needed

#### **Inactive Ingredients**

Cetostearyl alcohol, Cetomacrogal 1000, Light Liquid Paraffin, White Soft Paraffin

## **Principal Display**

Galzinc.jpg



ZINC OXIDE								
zinc oxide ointment								
Product Information								
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:50382-051				
Route of Administration	TOPICAL							
Active Ingredient/Active Moiety								
Ingredient Name Basis of Streng				ıgth	Strength			
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE				200 mg in 1 g				
Inactive Ingredients								
	Ingredient Name				Strength			

CET	OSTEARYL ALCO	HOL (UNII: 2DMT128M1S)					
CETI	<b>ETH-20</b> (UNII: 1835F	121HHX)					
LIGH	TT MINERAL OIL (	UNII: N6K5787QVP)					
PETI	ROLATUM (UNII: 47	Γ6 H12 B N9 U)					
Pac	kaging						
#	Item Code	Package Description	Marketing Start Date M		Ma	arketing End Date	
1 NI	DC:50382-051-03	72 in 1 CASE					
1		28.34 g in 1 TUBE					
2 NI	DC:50382-051-01	72 in 1 CASE					
2		56.68 g in 1 TUBE					
3 NI	DC:50382-051-02	12 in 1 CASE					
3		425.1 g in 1 JAR					
Ma	rketing Info	rmation					
Mar	rketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date	
отс	monograph final	art347		07/19/2013			

Labeler - Galentic Pharma (India) Priva Te Limited (918531450)

Establishment							
Name	Address	<b>ID/FEI</b>	<b>Business Operations</b>				
Galentic Pharma (India) Priva Te Limited		918531450	manufacture (50382-051)				

Revised: 7/2013

Galentic Pharma (India) Priva Te Limited