

**ZINC OXIDE- zinc oxide ointment**  
**Galentic Pharma (India) Private 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;
- poison ivy
- 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, Cetomacrogol 1000, Light Liquid Paraffin, White Soft Paraffin

**Principal Display**

Galzinc.jpg

NDC # 50382-051-01

# Galentic

## Zinc Oxide Ointment

Skin Protectant  
Net Wt. 1 OZ (28.4g)

Manufactured by Galentic Pharma  
 India Private Limited  
 Navi Mumbai, Maharashtra,  
 India 400701

| Drug Facts  | Drug Facts (continued)   | Drug Facts (continued)   |
|---|--|--|
| <b>Active Ingredients</b> (in each gram)<br>Zinc Oxide 200 mg .....Skin Protectant<br><br><b>Purpose</b><br>Skin Protectant<br><br><b>Uses:</b><br>■ Helps treat and prevent diaper rash<br>■ Dries the oozing and weeping of<br>■ poison ivy ■ poison oak ■ poison sumac<br><br><b>Warnings:</b><br><b>For external use only</b><br><b>When using this product</b> ■ do not get in eyes<br><br><b>Stop use and ask a doctor if:</b><br>■ condition worsens<br>■ symptoms last more than 7 days or clear up and occur again in a few days<br>■ you are allergic to any of these ingredients ▶ | <b>Do not use</b><br>■ over large areas of the body<br>■ on deep or puncture wounds<br>■ animal bites ■ serious burns<br><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.<br><br><b>Directions:</b><br><b>For diaper rash</b><br>■ change wet and soiled diapers promptly<br>■ cleanse the diaper area and allow to dry<br>■ Apply ointment liberally with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged<br><b>For poison Ivy and sumac</b><br>■ apply ointment liberally as often as needed ▶ | <b>Other information:</b><br>■ Store at room temperature 15°- 30° C (59°- 86° F)<br>■ Avoid excessive heat<br>■ See carton or tube crimp for lot number and expiration date.<br><br><b>Inactive Ingredients:</b><br>light mineral oil, white petrolatum<br><br>■ Made in India |

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

|  |  |
|--|--|
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) |  |
| CETETH-20 (UNII: I835H2IHHX)           |  |
| LIGHT MINERAL OIL (UNII: N6K5787QVP)   |  |
| PETROLATUM (UNII: 4T6H12BN9U)          |  |

| <b>Packaging</b> |                  |                     |                      |                    |
|------------------|------------------|---------------------|----------------------|--------------------|
| #                | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1                | NDC:50382-051-03 | 72 in 1 CASE        |                      |                    |
| 1                |                  | 28.34 g in 1 TUBE   |                      |                    |
| 2                | NDC:50382-051-01 | 72 in 1 CASE        |                      |                    |
| 2                |                  | 56.68 g in 1 TUBE   |                      |                    |
| 3                | NDC:50382-051-02 | 12 in 1 CASE        |                      |                    |
| 3                |                  | 425.1 g in 1 JAR    |                      |                    |

| <b>Marketing Information</b> |  |                      |                    |
|------------------------------|--|----------------------|--------------------|
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final          | part347                                  | 07/19/2013           |                    |

**Labeler** - Galentic Pharma (India) Private Limited (918531450)

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

Revised: 7/2013

Galentic Pharma (India) Private Limited