

**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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**Galentic GalShield Ointment**

Active Ingredient	Purpose
Zinc Oxide (1.8% w/w)	Skin Protectant

**Uses:**

- Helps treat and prevent diaper rash
- Temporarily protects
- minor cuts
- scrapes and
- burns
- 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:**

- condition worsens
- symptoms last more than 7 days or clear up and occur again in a few days, consult a physician

**Keep out of reach of children.**

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

**Dosage and Administration:**

For skin protectant:

- Apply liberally as needed

For diaper Rash:

- change wet and soiled diapers promptly
- allow to dry
- apply ointment liberally with each diaper change

**Other information:**

- Store at room temperature

- avoid excessive heat
- contains color additives including FDC yellow # 5

Indications and Usage: For use as a general skin protectant and diaper rash.

### **Inactive Ingredients**

Inactive ingredients:

Aloe Vera Leaf, Alpha-Tocopherol, Ceteth-10, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender, Methylparaben, Mineral Oil, Paraffin, Petrolatum, Phenoxyethanol, Polyethylene Glycol 6000, Polysorbate 60, Propylparaben Sodium, Steareth-20, Trolamine, Vitamin A, Water

### **Principal Display Panel**

Galentic GalShield

GalShield.jpg

NDC #50382-001-01

**Enhanced  
Formula**

# Galentic GalShield™

**Skin Protectant • Aloe Soft • Vitamin Enriched**

Reorder No. 1195  
Net Wt. 4 OZ (113g)

• Vitamin A • Vitamin D  
• Vitamin E • Zinc Oxide • Aloe Vera

### Drug Facts

**Active Ingredient**  
Zinc Oxide (1.8% w/w) ... Skin Protectant

**Purpose**

**Uses:**  
• Helps treat and prevent diaper rash.  
• Temporarily protects: • minor cuts  
• scrapes • burns

• Dries the oozing and weeping of:  
• poison ivy • poison oak • poison sumac

**Warnings • For External Use Only.**

**When using this product**

• Do not get into eyes

**Stop use and ask a doctor if:**

• Condition worsens • Symptoms last more than 7 days or clear up and occur again in a few days, consult a physician

**Keep out of reach of children**

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

**Directions:**

• Apply liberally as needed

• For diaper rash: • change wet and soiled diapers promptly • allow to dry

• Apply ointment liberally with each diaper change

**Other information:**

• Store at room temperature  
15° - 30°C (59° - 86°F)

• Avoid excessive heat

• Contains color additives including FD&C Yellow No. 5 (Tartrazine).

**Inactive ingredients** Aloe Vera Leaf, Alpha-Tocopherol, Ceteth-10, Cetostearyl Alcohol, Cetyl Alcohol, Cholecalciferol, Glycerin, Lanolin, Lavender, Methylparaben, Mineral Oil, Paraffin, Petrolatum, Phenoxethanol, Polyethylene Glycol 5000, Polysorbate 80, Propylparaben Sodium, Steareth-20, Trielamine, Vitamin A, Water

Manufactured for:  
Galentic Pharma India  
Private Limited  
Navi Mumbai,  
Maharashtra 400701  
Made in India

PATIENT NAME:

ROOM #

## ZINC OXIDE

zinc oxide ointment

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-011
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.8 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
LANOLIN (UNII: 7EV65EAW6H)	
CETETH-10 (UNII: LF9X1PN3XJ)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARETH-20 (UNII: L0Q8IK9E08)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
VITAMIN A (UNII: 81G40H8B0T)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PETROLATUM (UNII: 4T6H12BN9U)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-011-01	114 g in 1 TUBE		
2	NDC:50382-011-02	427.5 g in 1 JAR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	08/08/2013	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		918531450	manufacture(50382-011)

Revised: 8/2013

Galentic Pharma (India) Private Limited