

ZINC OXIDE AND DIMETHICONE WITH DIMETHICONE- zinc oxide and dimethicone cream

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.

Galsield Zinc Oxide / Dimethicone

Active ingredient	Purpose
Zinc Oxide (200 mg)	Diaper Rash
Dimethicone 1.8%	Skin Protectant

Purpose:

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

Warnings:

For external use only

Dosage and Administration:

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, oak and sumac

- apply ointment liberally as often as needed

Other information

- Do not use if seal is punctured or not visible
- store at room temperature 15°-30° C (59°-86° F)
- avoid excessive heat

Inactive ingredients

Aloe Barbadosis Leaf Juice, Cetyl Alcohol, Cholecaliferol, Diazolidinyl Urea, Fragrance, Lanolin, Methylparaben, Mineral Oil, Petrolatum, Purified Water, Retinyl Palmitate, Sodium Borate, Stearic Acid, Tocopheryl Acetate, Yellow 5, Yellow 6, Zea Mays (Corn) oil

Stop use if

- conditions worsen
- symptoms last more than 7 days or clear up and occur in a few days, consult a physician

- over large areas of the body
- if you are allergic to these ingredients

Indications and Usage

Indications are for diaper rash and general skin protectant.

Do not use

- 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.

Principal Display Panel

GalShield with Dimethicone

GalShield D.jpg

NDC #50382-012-01

**Enhanced
Formula**

Galentic
GalShield™
with Dimethicone

Reorder No.1199
Net Wt. 4 OZ (113g)

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

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

Drug Facts	Purpose
Active Ingredient (in each gram) Zinc Oxide (200 mg) Diaper Rash Dimethicone 1.8% 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 into eyes • condition worsens
Stop use and ask a doctor if	• 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
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, oak and sumac	• apply ointment liberally as often as needed
Other information:	• Do not use if seal is punctured or not visible • Store at room temperature 15° - 30°C (59° - 86°F) • Avoid excessive heat
Inactive Ingredients Aloe Vera Leaf, Alpha-Tocopherol, Ceteih-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	

PATIENT NAME:

ROOM #

ZINC OXIDE AND DIMETHICONE WITH DIMETHICONE

zinc oxide and dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	18 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
LANOLIN (UNII: 7EV65EAW6H)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0K00R)	
CETETH-10 (UNII: LF9X1PN3XJ)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYL PARABEN SODIUM (UNII: 625NNB0G9N)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARETH-20 (UNII: L0Q8IK9E08)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
VITAMIN A (UNII: 81G40H8B0T)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-012-01	113.4 g in 1 TUBE		

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)

Revised: 8/2013

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