

**HYDROCORTISONE- hydrocortisone 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.*

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**Galentic Hydrocortisone Cream 1%**

Active Ingredient	Purpose
Hydrocortisone Acetate 1%	Antipruritic (anti-itch)

**Purpose:**

For temporary relief of;

- minor skin irritations

Itching and rashes due to;

- eczema
- insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- detergents
- cosmetics
- jewelry

and for external itching of;

- genital
- feminine and
- anal itching

**Warnings:**

**For external use only**

**Do not use:**

- in the eyes
- longer than 1 week unless directed by a physician
- for diaper rash
- if you have vaginal discharge
- more than the recommended daily dosage unless directed by a doctor
- in the rectum by using fingers or any other mechanical device or applicator

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

- the condition persists or gets worse
- symptoms clear up and occur again within a few days
- you are pregnant or breast feeding

**Keep out of reach of children**

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

**Directions:****Adults and children over 2 years of age**

- Apply evenly to affected area no more than 3 or 4 times daily.

**Children under 2 years of age**

- Do not use
- consult a physician

**Adults**

- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- Gently dry, patting and blotting with bathroom tissue or soft cloth before applying
- apply externally to the area up to 6 times daily or after each bowel movement

**Other information:**

- Store at 20 deg - 25 deg C (68 deg - 77 deg F)
- Avoid excessive heat and humidity

**Inactive ingredients:**

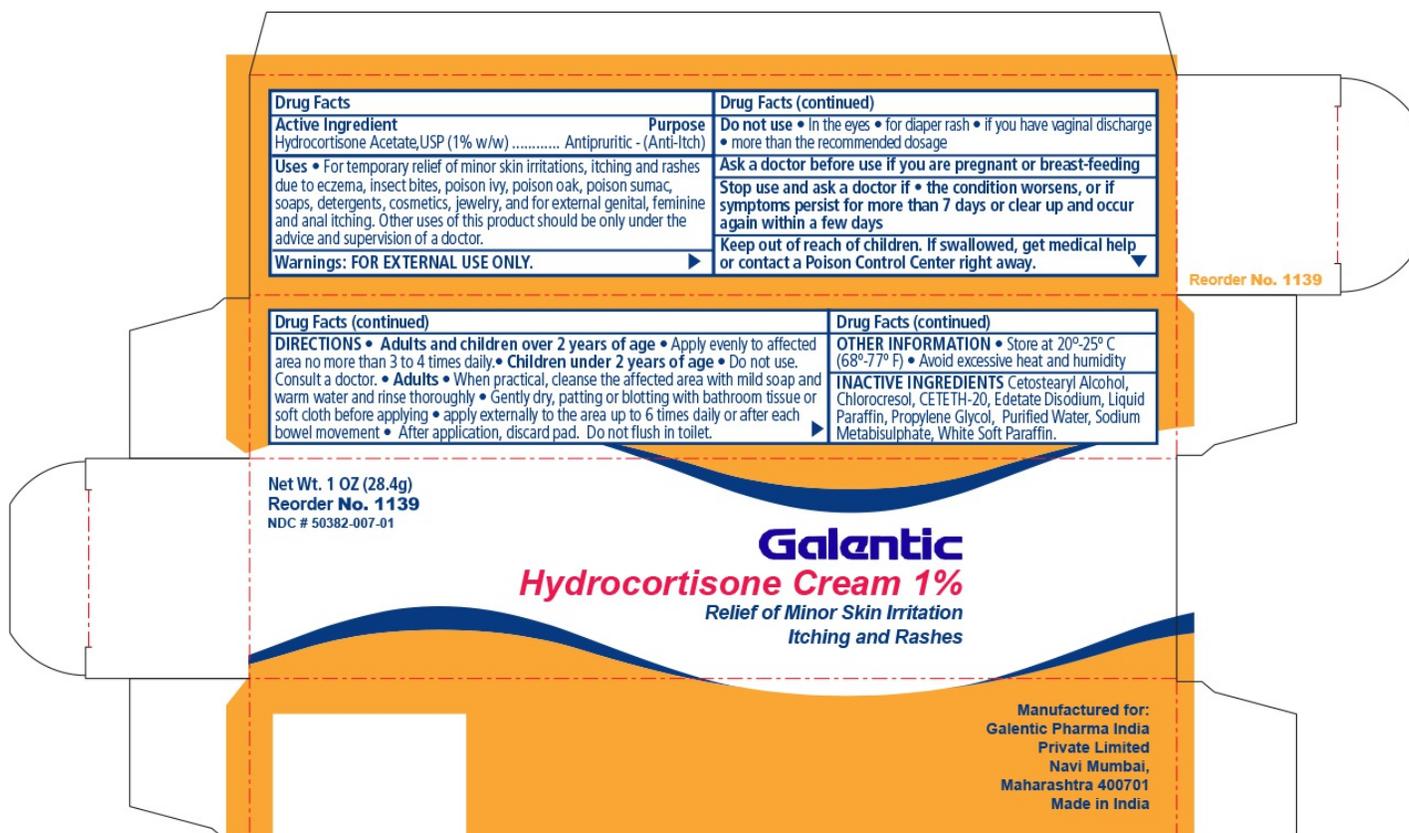
Cetomacrogol 1000, Cetostearyl Alcohol, Chlorocresol, Edetate Disodium, Liquid Paraffin, Propylene Glycol, Sodium Betabisulphite, White Soft Paraffin, Water (purified)

For temporary relief of minor skin irritations and external itching.

**Principal Display Panel**

Hydrocortisone 1%

Hydrocortisone Cream.jpg



## HYDROCORTISONE

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50382-010
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
CETETH-20 (UNII: I835H2IHHX)	
CETO STEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLORO CRESOL (UNII: 36W53O7109)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PETROLATUM (UNII: 4T6H12BN9U)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-010-01	28.3 g in 1 TUBE		
2	NDC:50382-010-02	425 g in 1 JAR		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/07/2013	

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

Revised: 8/2013

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