

**HYDROCORTISONE ACETATE- hydrocortisone acetate 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 Hydrocortisone Ointment 1%**

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

**Purpose**

Hydrocortisone is 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**

**Indications and Usage:**

- 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 bu using fingers or any other mechanical device or applicator
- For temporary relief of minor skin irritations and external itching.

**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.

**Dosage and Administration:****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

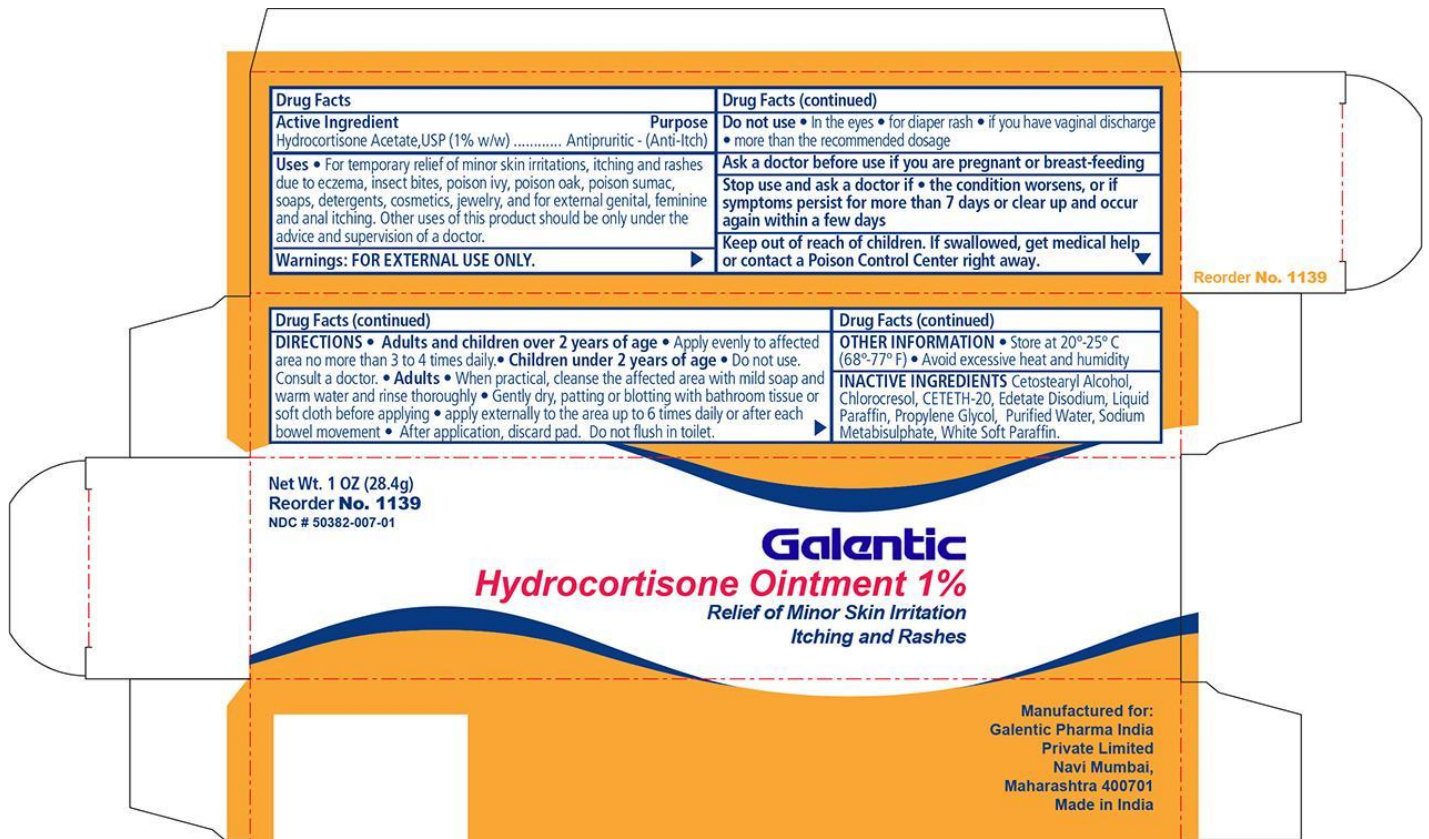
**Inactive ingredients:**

Liquid Paraffin, White Soft Paraffin

**Principal Display Panel**

Hydrocortisone

Gal Hydro Ointment.jpg



## HYDROCORTISONE ACETATE

hydrocortisone acetate ointment

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50382-007
<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
PARAFFIN (UNII: I9O0E3H2ZE)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50382-007-01	28.4 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/06/2011	

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

Revised: 8/2013

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