

**HYDROCORTISONE- hydrocortisone acetate cream**  
**Blossom Pharmaceuticals**

*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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**Blossom Pharmaceuticals Hydrocortisone Cream 1%**

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

**Warnings:**

**For external use only**

**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

**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 bu 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.

**Dosage & 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:**

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**

Blossom Pharmaceuticals Hydrocortisone 1%

Hydrocortisone.jpg

<b>Drug Facts</b>	<b>Drug Facts (continued)</b>
<b>Active Ingredient</b> Hydrocortisone Acetate, USP (1% w/w) ..... Antipruritic - (Anti-Itch)	<b>Purpose</b> Do not use • In the eyes • for diaper rash • if you have vaginal discharge • more than the recommended dosage
<b>Uses</b> • 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 genital, feminine and anal itching. Other uses of this product should be only under the advice and supervision of a doctor.	<b>Ask a doctor before use if you are pregnant or breast-feeding</b>
<b>Warnings: FOR EXTERNAL USE ONLY.</b>	<b>Stop use and ask a doctor if • the condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days</b>
	<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>

<b>Drug Facts (continued)</b>	<b>Drug Facts (continued)</b>
<b>DIRECTIONS</b> • Adults and children over 2 years of age • Apply evenly to affected area no more than 3 to 4 times daily. • Children under 2 years of age • Do not use. Consult a doctor. • Adults • When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly • Gently dry, patting or blotting with bathroom tissue or soft cloth before applying • apply externally to the area up to 6 times daily or after each bowel movement • After application, discard pad. Do not flush in toilet.	<b>OTHER INFORMATION</b> • Store at 20°-25° C (68°-77° F) • Avoid excessive heat and humidity
	<b>INACTIVE INGREDIENTS</b> Cetostearyl Alcohol, Chlorocresol, CETETH-20, Edetate Disodium, Liquid Paraffin, Propylene Glycol, Purified Water, Sodium Metabisulphate, White Soft Paraffin.

Net Wt. 1 OZ (28.4g)  
Reorder No. 1139  
NDC# 61767-224-01

**Hydrocortisone Cream 1%** *Blossom*  
Relief of Minor Skin Irritation  
Itching and Rashes  
PHARMACEUTICALS

AREA FOR LOT  
AND EXPIRATION

Manufactured by:  
Blossom Pharmaceuticals  
Karaswade, Tivim,  
Bardez, Tivi  
Gao, Goa  
India 403526  
Made in India

## HYDROCORTISONE

hydrocortisone acetate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61767-224
<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)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETETH-20</b> (UNII: I835H2IHHX)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CHLORO CRESOL</b> (UNII: 36W53O7109)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61767-224-01	72 in 1 CASE		
1		28.3 g in 1 TUBE		
2	NDC:61767-224-04	12 in 1 CASE		
2		425 g in 1 JAR		
3	NDC:61767-224-02	12 in 1 CASE		
3		144 in 1 BOX		
3		0.9 g in 1 PACKET		
4	NDC:61767-224-03	1728 in 1 CASE		
4		0.9 g in 1 PACKET		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2014	

**Labeler** - Blossom Pharmaceuticals (677381470)

Revised: 5/2014

Blossom Pharmaceuticals