

## **HYDROCORTISONE- hydrocortisone acetate cream**

**Dynarex Corporation**

*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.*

-----

### **Dynarex Hydrocortisone Cream 1%**

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

### **Warnings:**

**For external use only**

### **Purpose**

Use:

- For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and for external genital, feminine, and anal itching.

### **Do not use:**

- in the eyes
- for diaper rash
- for external genital or feminine itching if you have a vaginal discharge
- more than the recommended daily dosage unless directed by a doctor
- this product in the rectum by using fingers or any mechanical device or applicator

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

- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, and do not use this or any other hydrocortisone product.
- in case of bleeding when used for anal itching

### **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.

### **Directions:**

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.
- When used for anal itching, 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. Children under 12: consult a doctor before using for anal itching.

### **Other information:**

- Store at room temperature
- Avoid excessive heat

## Inactive ingredients:

Cetomacrogol 1000, Cetostearyl Alcohol, Chlorocresol, Liquid Paraffin, Propylene Glycol, Purified water, White Soft Paraffin.

For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and for external genital, feminine, and anal itching.

## Principal Display Panel

1137 Hydro Cort.jpg

Manufactured for: **NDC# 67777-224-02** **Reorder No. 1137**  
Dynarex Corporation  
Orangeburg, NY 10962  
www.dynarex.com  
Made in Israel

# Hydrocortisone Cream 1%

Relief of Minor Skin Irritation,  
Itching and Rashes



**144** Net Wt. 0.9 g  
Packets

### Drug Facts

Active Ingredient	Purpose
Hydrocortisone Acetate 1%	Antipruritic (Anti-Itch)

**Uses** For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and for external genital, feminine, and anal itching.

#### Warnings

For external use only

If pregnant or breast-feeding, ask a health professional before use

#### Do not use

- in the eyes
- for diaper rash
- for external genital or feminine itching if you have a vaginal discharge
- more than the recommended daily dosage unless directed by a doctor
- this product in the rectum by using fingers or any mechanical device or applicator

#### Stop use and ask a doctor if

- condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, and do not use this or any other hydrocortisone product.
- in case of bleeding when used for anal itching

### Drug Facts (continued)

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: consult a doctor.
- When used for anal itching, 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. Children under 12: consult a doctor before using for anal itching.

**Other Information** ■ Store at room temperature ■ Avoid excessive heat

**Inactive Ingredients** Cetareth-20, Cetostearyl Alcohol, Chlorocresol, Disodium EDTA, Mineral Oil, Propylene Glycol, Sodium Metabisulphite, Water, White Petrolatum

## HYDROCORTISONE

hydrocortisone acetate cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67777-224	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)		HYDROCORTISONE ACETATE	1 g in 100 g	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
CETETH-20 (UNII: I835H2IHHX)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)				
CHLOROCRESOL (UNII: 36W53O7109)				
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
SODIUM METABISULFITE (UNII: 4VON5FNS3C)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67777-224-01	28.3 g in 1 TUBE; Type 0: Not a Combination Product	02/02/2010	
2	NDC:67777-224-02	0.9 g in 1 PACKET; Type 0: Not a Combination Product	02/02/2010	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part348	02/02/2010		

**Labeler** - Dynarex Corporation (008124539)

**Registrant** - Dynarex Corporation (008124539)