

## **HYDROCORTISONE- hydrocortisone cream**

**Kinray Inc.**

*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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### **Hydrocortisone**

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

### **Warnings:**

**For external use only**

### **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

### **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

Inactive Ingredients: Cetostearyl alcohol, glyceryl monostearate, methylchloroisothiazolinone, propylene glycol, purified water, stearic acid, triethanolamine, white soft paraffin.

## Principal Display Panel

KR-1139

Hydrocortisone248.jpg




Drug Facts
Active Ingredient..... Purpose Hydrocortisone USP (1% w/w) ..... Antipruritic (Anti-Itch)
Uses: 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 only be under the advice and supervision of a doctor.
Warnings • FOR EXTERNAL USE ONLY • Ask a doctor before use if you are pregnant or breast-feeding
Do not use: • In the eyes • For the treatment of diaper rash • If you have vaginal discharge • More than the recommended dosage
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. Stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a physician.
Directions: • 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. • 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
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Other information • Store at 15°-30°C (59°-86°F) • Avoid excessive heat and humidity.
Inactive Ingredients: Cetostearyl Alcohol, Glyceryl Monostearate SE, Methylchloroisothiazolinone, Propylene Glycol, Purified Water, Stearic Acid, Triethanolamine, White Soft Paraffin.

† This product is not manufactured or distributed by 181 Healthcare, owner of the registered trademark Cortaid®.


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from retailer where purchased.  
Manufactured by: Dynarex Corp.  
Distributed by:  
Kinray, LLC WhiteStone, NY 11357

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NET WT. 1 OZ. (28.4 g)




**HYDROCORTISONE**  
**CREAM, 1%**  
**CREAM**

Compare to Cortaid®  
Sensitive Skin Cream™


Effective Relief of Itches and Rashes for  
Children and Adults Due To:  
Seborrheic Dermatitis • Eczema • Psoriasis • Poison Ivy,  
Oak, and Sumac • Insect Bites • Soaps • Detergents  
Cosmetics • Jewelry

**Itch & Rash Relief**  
**Safe for Children**

**HYDROCORTISONE**  
**CREAM, 1%**  
**MAXIMUM STRENGTH**



**CREAM**



## HYDROCORTISONE

hydrocortisone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63777-248
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
PARAFFIN (UNII: I9O0E3H2ZE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63777-248-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	06/14/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/14/2017	

**Labeler** - Kinray Inc. (012574513)

**Registrant** - Dynarex Corporation (008124539)

Revised: 6/2017

Kinray Inc.