# HYDROCORTISONE ACETATE- hydrocortisone acetate 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 Acetate 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**

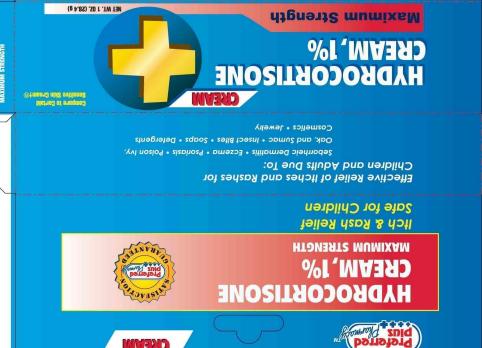
Inactive Ingredients: Cetomacrogol 1000, Cetostearyl alcohol, Chlorocresol, Edetate sodium, Liquid paraffin, Propylene glycol, Purified water, Sodium metabisulphate, White soft paraffin.

#### **Principal Display Panel**

KR-1139

Hydrocortisone.jpg





#### HYDROCORTISONE ACETATE

hydrocortisone acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63777-224
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDRO CORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII: WI4X0 X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
<b>CETETH-20</b> (UNII: 1835H2IHHX)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
CHLOROCRESOL (UNII: 36W53O7109)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
SODIUM METABISULFITE (UNII: 4VON5FNS3C)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
PETRO LATUM (UNII: 4T6 H12BN9 U)			
WATER (UNII: 059QF0KO0R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

Packaging					
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NE	OC:63777-224-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	09/06/2011	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	07/29/2011		

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

### **Registrant** - Dynarerx Corporation (008124539)

Establishment				
Name	Address	ID/FEI	Business Operations	
Galentic Pharma (India) Pvt. Ltd.		864201135	manufacture(63777-224)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Blossom Pharmaceuticals		677381470	manufacture(63777-224)	

Revised: 5/2016 Kinray Inc.