

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.

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

NDC # 63777-224-01

CREAM

HYDROCORTISONE CREAM, 1%

Maximum Strength



Drug Facts

Active Ingredient **Purpose**
 Hydrocortisone Acetate, 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 • After application, discard pad.

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

Other information • Store at 20°-25°C (68°-77°F) • Avoid excessive heat and humidity.

Inactive Ingredients: Cetomacrogol 1000, Cetostearyl Alcohol, Chlorocresol, Edetate Disodium, Liquid Paraffin, Propylene Glycol, Purified Water, Sodium Metabisulphate, White Soft Paraffin.

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

HYDROCORTISONE CREAM, 1% MAXIMUM STRENGTH



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Distributed by:
 Kinray Inc. Whitestone, NY 11357

Manufactured by: Dynarex Corp.
 from retailer where purchased.
 satisfaction guaranteed or your money back

NO COPY / NO COLOR
 THIS BOX IS FOR LOT #
 AND EXP DATE PRINT

Maximum Strength

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

HYDROCORTISONE CREAM, 1% MAXIMUM STRENGTH

**Itch & Rash Relief
 Safe for Children**

CREAM

NET WT. 1 OZ. (28.4 g)

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
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W53O7109)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC: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** - Dynarex 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)