

HYDROCORTISONE- hydrocortisone 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 1%	Antipruritic (anti-itch)

Warnings

☐ **For external use only**

Purpose

For temporary relief of:

- minor skin irritations

Itches 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 recommended daily dosage unless directed by a doctor
- in the rectum 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 appear 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.

Directions :**Adults and children 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

□

Inactive ingredients :

Cetomacrogol 1000, cetostearyl alcohol, chlorocresol, edetate disodium, liquid paraffin, propylene glycol, sodium betabisulphate, white soft paraffin, water (purified)

Other information:

- store at 20 deg. to 25 deg. C (68 deg. - 77 deg. F)
- avoid excessive heat and humidity

For temporary relief of minor skin irritations and external itching.

Principal Display Panel

Dynarex Hydrocortisone Items 1137 and 1139

Hydro1139.jpg

Drug Facts	Drug Facts (continued)
Active Ingredient Hydrocortisone USP (1% w/w) Antipruritic - (Anti-Itch)	Purpose Do not use • In the eyes • for diaper rash • if you have vaginal discharge • more than the recommended dosage
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 be only under the advice and supervision of a doctor.	Ask a doctor before use if you are pregnant or breast-feeding
Warnings: FOR EXTERNAL USE ONLY.	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
	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)	Drug Facts (continued)
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. • 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	OTHER INFORMATION • Store at 20°-25° C (68°-77° F) • Avoid excessive heat and humidity
	INACTIVE INGREDIENTS 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 # 67777-415-01

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



Manufactured for:
Dynarex Corporation
Orangeburg, NY 10962
www.dynarex.com
Made in India

HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-415
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

ceteth-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-415-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	12/02/2015	
2	NDC:67777-415-02	0.9 g in 1 PACKET; Type 0: Not a Combination Product	12/02/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/02/2015	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Establishment

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Pvt. Ltd.		650970176	manufacture(67777-415)

Revised: 5/2016

Dynarex Corporation