

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

Uses: For 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 external 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 doctor if:

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

☐ **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 evenly to affected area no more than 3 or 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 and blotting with bathroom tissue or soft cloth before applying. Children under 12: consult doctor before using for anal itching.

☐

Inactive ingredients:

Cetostearyl alcohol, glyceryl monostearate, methylchloroisothiazolinone, propylene glycol, purified water, stearic acid, trolamine, white soft paraffin

Other information:

- store at room temperature
- avoid excessive heat

For temporary relief of minor skin irritations and external itching.

Principal Display Panel

Dynarex Hydrocortisone Items 1137 and 1139

Hydro 1139.jpg

Drug Facts	
Active Ingredient Hydrocortisone USP 1%	Purpose 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 <ul style="list-style-type: none"> ■ 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 	
Drug Facts (continued) Stop use and ask a doctor if <ul style="list-style-type: none"> ■ 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. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions <ul style="list-style-type: none"> ■ 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. 	

Reorder No. 1139
 NDC # 67777-417-01
 Manufactured for:
 Dynarex Corporation
 Orangeburg, NY 10962
 www.dynarex.com
 Made in India

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



Net Wt. 1 oz. (28.4 g)

Drug Facts (continued)

- 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 Cetostearyl Alcohol, Glyceryl Monostearate SE, Methylchloroisothiazolinone, Propylene Glycol, Purified Water, Stearic Acid, Triethanolamine, White Soft Paraffin.

HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-417
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)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PARAFFIN (UNII: I9O0E3H2ZE)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-417-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	10/07/2016	
2	NDC:67777-417-02	0.9 g in 1 PACKET; Type 0: Not a Combination Product	10/07/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/07/2016	

Labeler - Dynarex Corporation (008124539)**Registrant** - Dynarex Corporation (008124539)**Establishment**

Name	Address	ID/FEI	Business Operations
Gopaldas Visram & Co.,Ltd		858030888	manufacture(67777-417)

Revised: 6/2017

Dynarex Corporation