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.

Hydrocortisone

Active Ingredient Purpose

Hydrocortisone USP 10 mg Antipruritic (anti-itch)

Uses:

For temporary relief of;

- minor skin irritations, inflammation and rashes due to
- eczema
- insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- detergents
- cosmetics
- jewelry
- seborrheic dermatitis
- psoriasis
- scrapes

and for external itching of;

- genital
- feminine and
- anal itching
- other uses of this product should be only under the advice and supervision of a doctor

Warnings:

For external use only

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

Directions:

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 a controlled room temperature 15 deg 30 deg C (59 deg 86 deg F)
- Avoid excessive heat and humidity
- tamper evident, do not use if packet is torn, cut or open

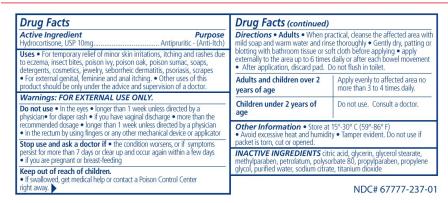
Inactive ingredients:

citric acid, glycerin, glycerol stearate, methylparaben, petrolatum, polysorbate 80, propyl paraben, propylene glycol, purified water, sodium citrate, titanium dioxide,

Indications and Usage

For temporary relief of minor skin irritations and external itching.

Principal Display



Made in USA



Hydrocortisone Cream 1%

Relief of Minor Skin Irritation
Itching and Rashes

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

Reorder No. 1137



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HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:67777-237

Route of Administration TOPICAL

Active Ingredient/Active Moiety

- 1	8		
	Ingredient Name	Basis of Strength	Strength
	HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0	OX7BPJ) HYDROCORTISONE	1 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)				
GLYCERIN (UNII: PDC6A3C0OX)				
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)				
METHYLPARABEN (UNII: A218 C7H19 T)				
PETROLATUM (UNII: 4T6H12BN9U)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
WATER (UNII: 059QF0KO0R)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:67777-237-01	12 in 1 CASE				
1	144 in 1 BOX				
1	0.9 g in 1 PACKET				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part348	02/02/2010				

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Revised: 3/2011 Dynarex Corporation