

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

Drug Facts	
Active Ingredient Hydrocortisone, USP 10mg.....	Purpose 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, seborrheic dermatitis, psoriasis, scrapes • For external 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 dosage • longer than 1 week unless directed by a physician • in the rectum by using fingers or any other mechanical device or applicator	
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 • if 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. ▶	

Drug Facts (continued)	
Directions • 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 • After application, discard pad. Do not flush in toilet.	
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.
Other Information • Store at 15°-30° C (59°-86° F) • Avoid excessive heat and humidity • Tamper evident. Do not use if packet is torn, cut or opened.	
INACTIVE INGREDIENTS citric acid, glycerin, glycerol stearate, methylparaben, petrolatum, polysorbate 80, propylparaben, propylene glycol, purified water, sodium citrate, titanium dioxide	

NDC# 67777-237-01

Made in USA

144
Packets

Net Wt 0.9 gram

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

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

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	
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)