

HYDROCORTISONE- antipruritic (anti-itch) 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.

1137 Hydrocortisone Cream NDC 67777-003-01

Active Ingredient

Hydrocortisone Acetate 1%

Purpose

Antipruritic (Anti-Itch)

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 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

- 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

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, and do not use this or any other hydrocortisone product.
- in case of bleeding when used for anal itching

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 time 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 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

Cetareth-20, Cetostearyl Alcohol, Chlorocresol, Disodium EDTA, Mineral Oil, Propylene Glycol, Sodium Metabisulfite, Water, White Petrolatum

1137 Label



HYDROCORTISONE

antipruritic (anti-itch) cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
MINERAL OIL (UNII: T5L8T28FGP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLOROCRESOL (UNII: 36W5307109)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-003-01	1728 in 1 CASE	05/03/2018	
1	NDC:67777-003-02	144 in 1 BOX		
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/03/2018	

Labeler - Dynarex Corporation (008124539)

Revised: 12/2022

Dynarex Corporation