

SIONBIOTEXT HYDROCORTISONE- hydrocortisone acetate 1% cream
Sion Biotext Medical Ltd

Active Ingredient (In Each Gram)

Hydrocortisone Acetate 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 oak
- poison sumac
- detergents
- cosmetics
- jewelry
- seborrheic
- dermatitis
- psoriasis
- for external genital
- feminine
- anal itching

Warnings

For external use only

Do not use

- in the eyes
- for diaper rash
- for external genital or feminine itching if you have a vaginal discharge
- more than the recommend daily dosage unless directed by a doctor
- this product in the rectum by using fingers or any other mechanical device or applicator
- if the seal is torn or if the tube is damaged

Stop use and ask a doctor if

- condition worsens, or if symptoms persists for more than 7 days or clears up and

occurs 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 pregnant or breastfeeding

ask a health professional before use

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 to affected area not more than 3 to 4 times daily.
- children under 2 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.

Other Information

- Store at 15°-30°C (59°-86°F)
- avoid excessive heat and humidity

Inactive Ingredients

Ceteareth 20, Cetostearyl Alcohol, Chlorocresol, Disodium EDTA, Mineral Oil, Propylene Glycol, Sodium metabisulfite, Water, White Petrolatum

Questions

info@sionbrands.com

Unclassified Section

Distributed by: SlonBrands LLC

16950 Via de Santa Fe, Rancho Santa Fe, CA, 92067

Mail Address: PO Box 450638, Laredo, TX, 78045

Email: info@sionbrands.com

Made in India

Principal Display Panel

NDC 68786-001-28

SIONBIOTEXT

Hydrocortisone Cream 1%

Relief of Minor Skin Irritation Itching and Rashes

For Personal and Professional Use

Net Wt: 1.0 oz (28.3g)



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Drug Facts

Active Ingredient (In Each Gram)	Purpose
Hydrocortisone Acetate 1%	Antipruritic (Anti-Itch)
Uses • For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison oak, poison sumac, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and for external genital, feminine and anal itching.	
Warnings • For external use only • 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 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, and do not use this or any other hydrocortisone product • in case of bleeding when used for anal itching • If pregnant or breastfeeding, ask a health professional before use • Keep out of reach of children • if swallowed get medical help or contact a Poison Control Center right away.	



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Drug Facts (continued)

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Inactive Ingredients • Cetareth 20, Cetostearyl Alcohol, Chlorocresol, Disodium EDTA , Mineral Oil, Propylene Glycol, Sodium metabisulfite, Water, White Petrolatum.

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Questions? info@sionbrands.com

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SIONBIOTEXT HYDROCORTISONE

hydrocortisone acetate 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68786-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)			HYDROCORTISONE ACETATE	0.1 g in 1 g
Inactive Ingredients				
Ingredient Name				Strength
CETEARETH-20 (UNII: YRC528SWJY)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
CHLOROCRESOL (UNII: 36W53O7109)				
EDETATE SODIUM (UNII: MP1J8420LU)				
MINERAL OIL (UNII: T5L8T28FGP)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM METABISULFITE (UNII: 4VON5FNS3C)				
WATER (UNII: 059QF0KO0R)				
WHITE PETROLATUM (UNII: B6E5W8RQJ4)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68786-001-28	28.3 g in 1 BOX; Type 0: Not a Combination Product	05/13/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M017	05/13/2025	

Labeler - Sion Biotext Medical Ltd (532775194)