

HYDROCORTISONE- hydrocortisone cream
ALLIED TRADE LINK LLC

HYDROCORTISONE

Purpose
 Hydrocortisone USP 1%

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

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
 Ask a doctor before use if you are using any other hydrocortisone product
 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 continue to use this or any other hydrocortisone product for longer than 7 days)
 Bleeding occurs due to anal itching

inactive Ingredients Aloe Vera, Cetostearyl Alcohol, Glyceryl Monostearate SE, Methylchloroisothiazolinone, Propylene Glycol, Purified Water, Stearic Acid, Trolamine, White Petrolatum

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

antipruritic (Anti-Itch)



hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84387-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84387-005-01	28.4 g in 1 TUBE; Type 0: Not a Combination Product	11/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	11/12/2024	

Labeler - ALLIED TRADE LINK LLC (029033682)

Registrant - ALLIED TRADE LINK LLC (029033682)

Establishment

Name	Address	ID/FEI	Business Operations
GOLPALDAS VISRAM AND COMPANY LIMITED		858030888	manufacture(84387-005)

Revised: 11/2024

ALLIED TRADE LINK LLC