ADVANCED HYDROCORTISONE- hydrocortisone cream
Ultra Seal 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.

Drug Facts

Active Ingredients (in each gram) Hydrocortisone USP-10 mg

Purpose: Antipruritic (Anti Itch)

For the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema,insect bites, poison ivy, poison oak, poison sumac, detergents, cosmetics, jewelry, saborrheic dermatitis, psoriasis and scrapes. For external feminine, genital, and anal itching. Other uses of this product should be only under the advice and supervision of a doctor.

For external use only. Do not use for the treatment of diaper rash.

Consult a doctor before use if :you have a vaginal discharge (for external feminine itching). For external itching, do not exceed the recommended daily dosage or if bleeding occurs. If condition worsens or symptoms persist more than 7 days or clear up and occur again within a few days.

When using this product: Avoid contact with eyes, do not put this product into rectum using fingers or any mechanical device or applicator

Do not use with any other hydrocortisone product unless you have consulted a doctor

Directions: For adults and children 2 years of age and older: Apply to affected area not more than 3-4 times daily

Children under 2 years of age: Do not use, consult a doctor.

Adults for external itching, when practical, cleanse the affected area with mild soap and warm water and rinse th

thoroughly or by patting or blotting with an appropriate cleansing pad

Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product

Children under 12 years of age-For external anal itching, consult a doctor

Inactive Ingredients: Citric Acid, Glycerin, Glycerol Stearate, Methylparaben, Petrolatum, Polysorbate 80, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate, Titanium Dioxide

Keep out of reach of children

ADVANCED HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42213-370
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**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
PETROLATUM (UNII: 4T6H12BN9U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42213-370-09	0.9 g in 1 PACKET; Type 0: Not a Combination Product	04/05/2011	07/01/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/05/2011	07/01/2024

Labeler - Ultra Seal Corporation (085752004)

Registrant - Ultra Seal Corporation (085752004)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRAtab Laboratories, Inc.		151051757	manufacture(42213-370)

Revised: 1/2023 Ultra Seal Corporation