HYDROCORTISONE- hydrocortisone cream
ADVANCED FIRST AID, INC.

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.

ACTIVE INGREDIENT (in each gram)- Hydrocortisone USP 10mg

Antipruritic (Anti-Itch)

Uses:

• 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, soaps, detergents, cosmetics, jewelry,

seborrheic dermatitis, psoriasis and 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 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 if symptoms persist for 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 by using

fingers or any mechanical device or applicator

Do Not Use: • with any other Hydrocortisone product unless you have consulted a doctor.

KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control

Center right away.

Directions: • For adults and children 2 years of age and older: apply to affected area 1 to 2 times

daily. • Children under 2 years of age: do not use, consult a doctor. • Adults for external anal itching

when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly or by

patting or blotting with an appropriate cleansing pad. • Gently dry by patting or blotting with toilet tissue or a

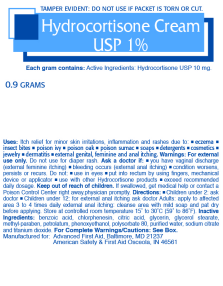
soft cloth before application of this product. • Children under 12 years of age: for external anal itching,

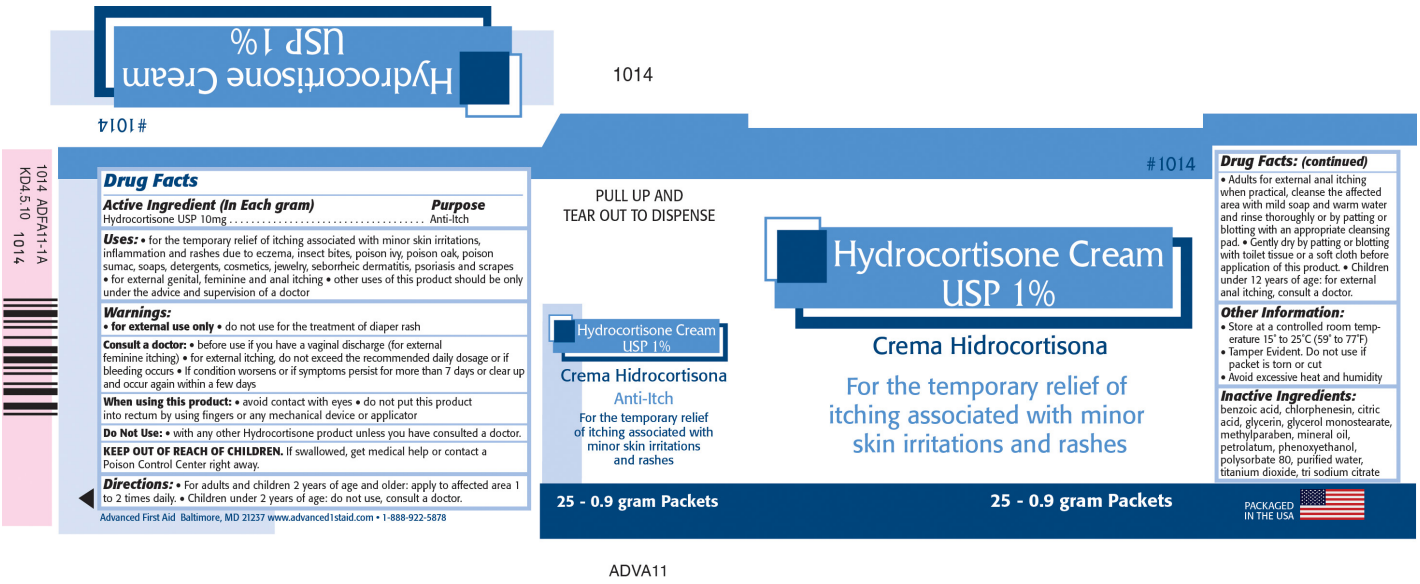
consult a doctor.

Inactive Ingredients:

citric acid, glycerin, glycerol stearate, methyl paraben, petrolatum, polysorbate 80, propylene glycol, propyl

paraben, purified water, sodium citrate and titanium dioxide.





HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67060-370
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:67060-370-39	25 in 1 CARTON	04/08/2015	07/01/2024
1	NDC:67060-370-09	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	04/08/2015	07/01/2024

Labeler - ADVANCED FIRST AID, INC. (114477180)

Registrant - ADVANCED FIRST AID, INC. (114477180)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA SEAL CORPORATION		085752004	pack(67060-370)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA TAB LABORATORIES, INC.		151051757	manufacture(67060-370)

Revised: 1/2023 ADVANCED FIRST AID, INC.