HYDROCORTISONE - hydrocortisone acetate cream Choice Laboratories

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.

Hydrocortisone Cream 1%

Active Ingredient	Purpose
Hydrocortisone Acetate 1%	Antipruritic (anti-itch)

Uses:

For temporary relief of;

• minor skin irritations

Itching and rashes due to;

- eczema
- insect bites
- poisonivy
- poison oak
- poison sumac
- soaps
- detergents
- cosmetics
- jewelry

and for external itching of;

- genital
- feminine and
- anal itching

Warnings:

For external use only

Do not use:

- in the eyes
- longer than 1 week unless directed by a physician
- for diaper rash
- if you have vaginal discharge
- more than the recommended daily dosage unless directed by a doctor
- in the rectum bu using fingers or any other mechanical device or applicator

Stop use and ask a physician if:

- the condition persists or gets worse
- symptoms clear up and occur again within a few days
- you are pregnant or breast feeding

Keep out of reach of children

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

Directions:

Adults and children over 2 years of age

• Apply evenly to affected area no more than 3 or 4 times daily.

Children under 2 years of age

- Do not use
- consult a physician

Adults

- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- Gently dry, patting and blotting with bathroom tissue or soft cloth before applying
- apply externally to the area up to 6 times daily or after each bowel movement

Other information:

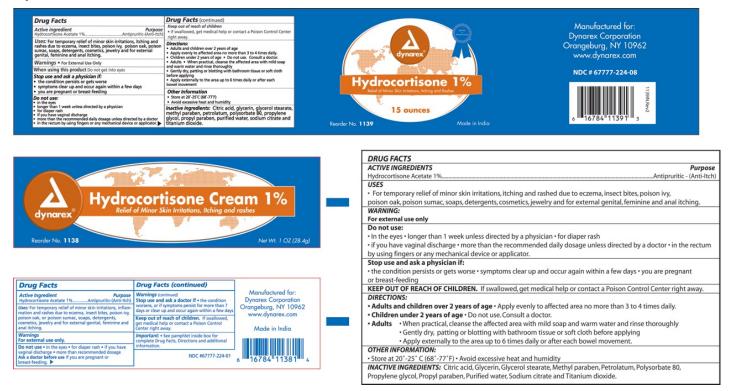
- Store at 20 deg 25 deg C (68 deg 77 deg F)
- Avoid excessive heat and humidity

Inactive ingredients:

Citric acid, Glycerin, Glycerol sterate, Methylparaben, Petrolatum, Polysorbate 80, Propylene Glycol, Propylparaben, Sodium citrate, Titanium dioxide, Water (purified)

Principal Display Panel

Hydrocortisone Cream 1%



HYDROCORTISC	DNE						
hydrocortisone acetate cream							
Product Information							
Product T ype	HUMAN OTC DRUG	Ite m C	Item Code (Source)			NDC:63174-224	
Route of Administration	TOPICAL						
Active Ingredient/Act	tive Moiety						
	Ingredient Name			Basis of S	trength	Strength	
HYDRO CORTISONE ACET UNII:WI4X0X7BPJ)	ETATE (UNII: 3X7931PO74) (HYDROCORTISONE - HYDROCORTISON ACETATE			ONE	1 g in 100 g		
Inactive Ingredients							
Ingredient Name				Str	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)							
GLYCERIN (UNII: PDC6A30							
GLYCERYL MONOSTEAR							
METHYLPARABEN (UNII: A							
PETROLATUM (UNII: 4T6 H							
POLYSORBATE 80 (UNII:)							
PROPYLENE GLYCOL (UN							
SODIUM CITRATE (UNII: 10							
TITANIUM DIO XIDE (UNII:							
WATER (UNII: 059QF0KO0	R)						
Packaging							
# Item Code	Package Description	Marketing Start Date Mar		arketing Er	rketing End Date		
1 NDC:63174-224-01	72 in 1 CASE						
1	28.3 g in 1 TUBE						
2 NDC:63174-224-08	12 in 1 CASE						
2	425 g in 1 JAR						
Marketing Information							
Ū	Application Number or Monogra	n Number or Monograph Citation Mar		Aarketing Start Date		Marketing End Date	
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Labeler - Choice Laboratories (650070394)

Name	Address	ID/FEI	Business Operations
Choice Laboratories		650070394	manufacture

Revised: 2/2010

Choice Laboratories