GADADERM HYDROCORTISONE- hydrocortisone acetate cream
Gadal Laboratories 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	**Purpose**
Hydrocortisone Acetate (0.5%)	Antiruritic (Anti-itch)

Purpose

Antipruritic (Anti-itch)

Uses

For temporary relief of minor skin irritations and rashes due to eczema, insect bites, poison oak, poison sumac, poison ivy, soaps, detergents, cosmetics, jewelry, and for external genital, feminine and anal itchin. Other uses of this product should be only under the advice and supervision of doctor.

Warnings: For External Use Only.

Do not use
- in the eyes
- for diaper rash
- if you have vaginal discharge
- more than recommended dosage

Stop use and ask a doctor if
- the condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Ask a doctor before use if 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

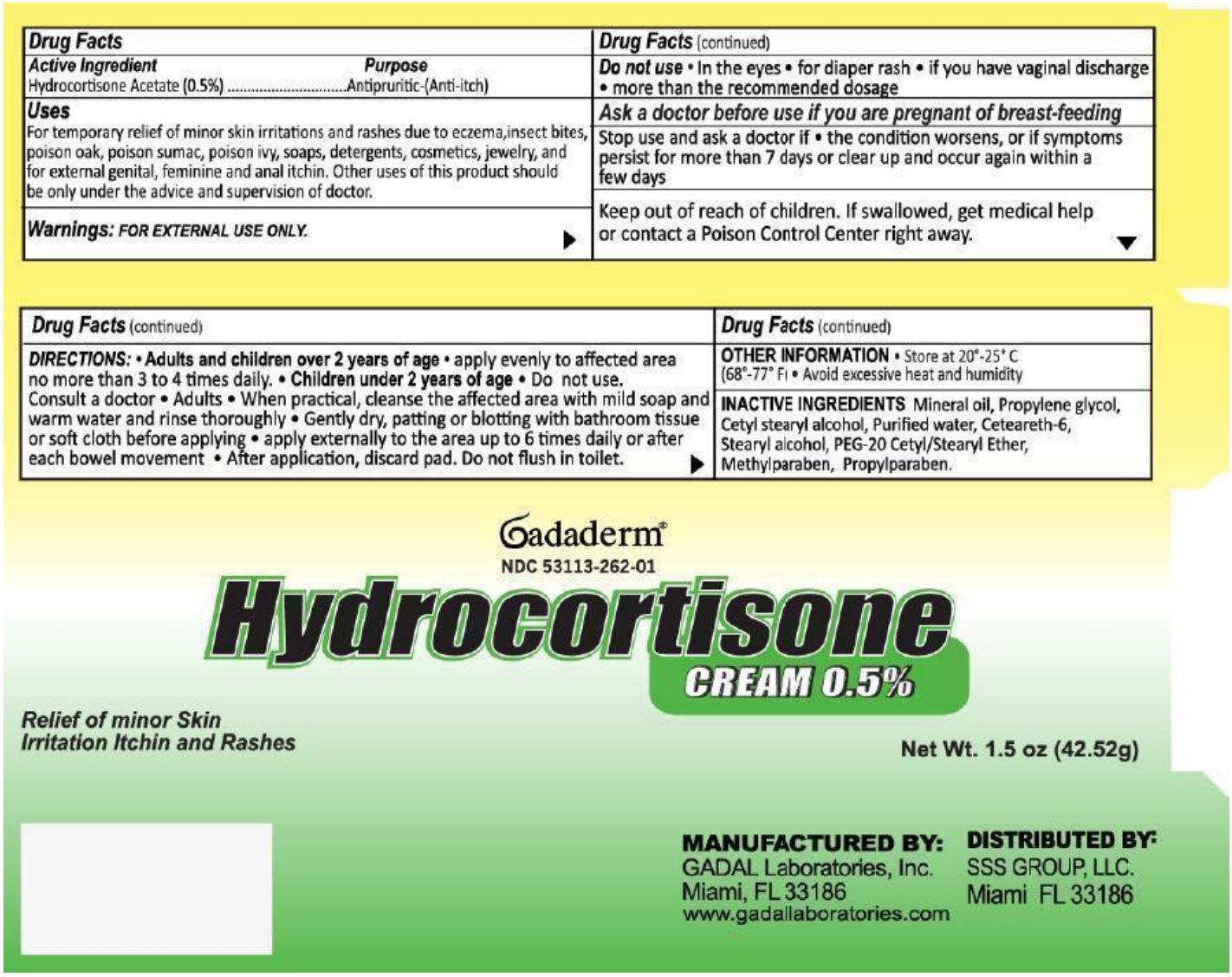
Directions
- **Adults and children over 2 years of age:** apply evenly to affected area no more than 3 to 4 times daily
- **Children under 2 years of age**: Do not use. Consult a doctor

Adults: When practical, 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. Apply externally to the area up to 6 times daily or after each bowel movement. After application, discard pad. Do not flush in toilet.

Inactive ingredients Mineral oil, propylene glycol, cety stearyl alcohol, purified water, ceteareth-6,

stearyl alcohol, PEG-20 cetyl/stearyl ether, methylparaben, propylparaben

GADAL Laboratories, Inc.
Miami, Fl 33186
www.gadallaboratories.com



GADADERM HYDROCORTISONE

hydrocortisone acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53113-262
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE -	HYDROCORTISONE	0.5 g

UNII:WI4X0X7BPJ)	ACETATE	in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WATER (UNII: 059QF0KO0R)	
CETEARETH-6 (UNII: 2RJS3559D3)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-262-01	1 in 1 BOX		
1		42.52 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/01/2013	

Labeler - Gadal Laboratories Inc (841305639)

Revised: 9/2013 Gadal Laboratories Inc