HYDROCORTISONE- hydrocortisone cream
NuCare Pharmaceuticals,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.

Hydrocortisone Maximum Strength

Drug Facts

Active ingredient

Hydrocortisone, USP 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to
  - eczema
  - psoriasis
  - insect bites
  - poison ivy, oak, sumac
  - detergents
  - jewelry
  - cosmetics
  - soaps
  - seborrheic dermatitis
- temporarily relieves external anal and genital 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

- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

When using this product

- avoid contact with the eyes
- do not use more than directed unless directed by a doctor

- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if
- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days
- do not begin the use of any other hydrocortisone product unless directed by a doctor
- rectal bleeding occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions
- for itching of skin irritation, inflammation, and rashes
  - adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
  - children under 2 years of age: consult a doctor
- for external anal and genital itching
  - adults: when practical, clean the affected area with mild soap and warm water; rinse thoroughly
  - gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
  - apply to affected area not more than 3 to 4 times daily
  - children under 12 years of age: consult a doctor

Other information
- store at 15°-30°C (59°-86°F). Protect from freezing.
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

cetyl alcohol, citric acid [1], glyceryl stearate, isopropyl myristate, methylparaben, polyoxyl 40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate solution [1], sorbic acid, sorbitan monostearate, stearyl alcohol, white wax

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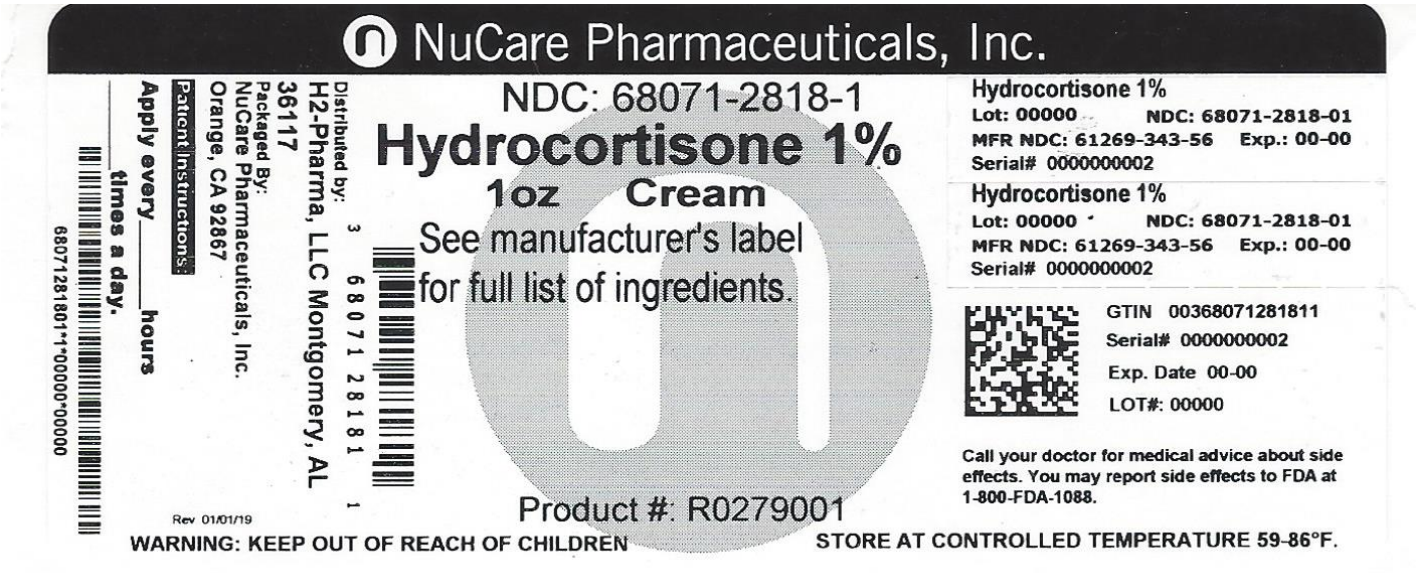
1 Contains one or more of these ingredients to adjust pH

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117

PRINCIPAL DISPLAY PANEL



HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-2818(NDC:61269-343)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WHITE WAX (UNII: 7G1J5DA97F)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68071-2818-1	1 in 1 CARTON	08/23/2022	
1		28 g in 1 TUBE; 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	06/29/2021	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-2818)

Revised: 8/2022 NuCare Pharmaceuticals,Inc.