HYDROCORTISONE MAXIMUM STRENGTH- 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 Cream

Drug Facts

Active ingredient

Hydrocortisone, USP 1%

Purpose

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

•jewelry •detergents •cosmetics •psoriasis •seborrheic dermatitis

•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 external feminine itching 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 begin the use of any other hydrocortisone product unless directed by a doctor

•for external anal itching: •do not use more than directed unless directed by a doctor

•do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

•symptoms last for more than 7 days •the condition gets worse •symptoms clear up and occur again in a few days •rectal bleeding occurs, consult doctor promptly

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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 •do not use, consult a doctor
For external anal itching
Adults: when practical, clean the affected area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet issue or a soft cloth before application of this product
Children under 12 years of age: consult a doctor

OTHER INFORMATION

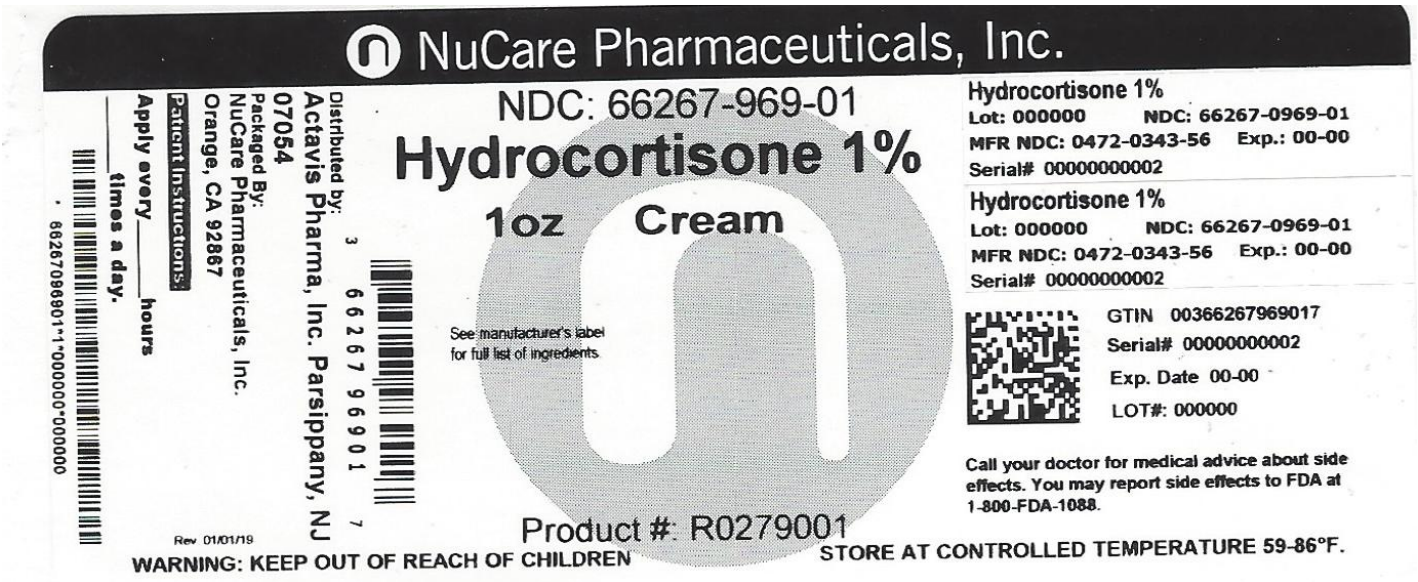
- Store at room temperature 59°-86°F (15°-30°C). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

cetyl alcohol, glyceryl stearate, isopropyl myristate, methylparaben, polyoxyl 40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sorbic acid, sorbitan monostearate, stearyl alcohol, white wax. May contain citric acid or sodium citrate solution to adjust pH.

Questions? **1-800-432-8534 between 9 am and 4 pm EST, Monday – Friday.**

PRINCIPAL DISPLAY PANEL



HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:66267-969(NDC:0472-0343)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	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)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66267-969-01	30 g in 1 BOX; Type 0: Not a Combination Product	07/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/01/1997	

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(66267-969)

Revised: 1/2021 NuCare Pharmaceuticals,Inc.