

## **HYDROCORTISONE D- hydrocortisone cream**

**NexMed (USA), 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.*

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### **Drug Facts**

#### **Active Ingredient**

Hydrocortisone 1%

#### **Purpose**

Anti-itch cream

#### **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, 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.

#### **When using this product**

- avoid contact with the eyes
- do not put this product 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, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

#### **Do not use**

- for the treatment of diaper rash. Ask a doctor
- in the genital area if you have vaginal discharge. Ask 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 not more than 3 to 4 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 toilet tissue or a soft cloth before application of this product
- Children under 12 years of age: for external itching consult a doctor

**Other information**

Store between 20° and 25°C (68° to 77°F)

**Inactive Ingredients**

citric acid, dodecyl-2-N N-dimethylaminopropionate hydrochloride, glycerin, glycerol stearate, methylparaben, petrolatum, polysorbate 80, propylene glycol, propylparaben, purified water, sodium citrate, titanium dioxide

**Questions?**

Call 1-800-866-7391, Mon-Fri, 8:30 AM - 5:30 PM (PST)



HYDROCORTISONE D			
hydrocortisone cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:40002-003
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	1 g in 100 g	

## Inactive Ingredients

Ingredient Name	Strength
<b>Citric Acid Monohydrate</b> (UNII: 2968PHW8QP)	
<b>Dodecyl-2-N,N-Dimethylaminopropionate Hydrochloride</b> (UNII: 18F5YMF989)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40002-003-02	1 in 1 CARTON		
1	NDC:40002-003-03	28 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/19/2011	

**Labeler** - NexMed (USA), Inc. (031710528)

**Registrant** - NexMed (USA), Inc. (031710528)