### DUANE READE - hydrocortisone cream Duane Reade

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.....Purpose

Enter section text here

#### Uses

temporary relief of itching associated with minor skin irritations and rashes due to

- eczema
- insect bites
- poison ivy, poison oak, or poison sumac
- soaps
- detergents
- cosmetics
- jewelry
- seborrheic dermatitis
- psoriasis
- external genital 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

- in the eyes
- by putting this product into the rectum by using fingers or any mechanical device or applicator

#### Ask a doctor before use if you have

- a vaginal discharge
- rectal bleeding
- diaper rash

#### When using this product

consult a doctor before exceeding recommended dosage

#### Stop use and ask a doctor if

- condition gets worse
- conditions persists for more than 7 days
- condition clears up and occurs again within a few days.

Do not begin to use any other hydrocortisone product unless you have consulted a doctor.

#### 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 12 years of age: consult a doctor.

#### For external anal itching:

- Adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a. soft cloth before application of this

Children under 12 years of age: consult a doctor.

#### Other information

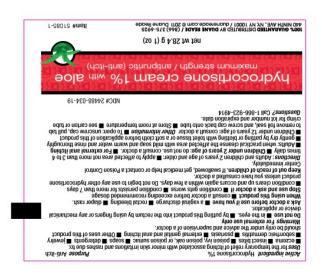
- To open: unscrew cap, pull tab to remove foil seal, and screw cap back onto tube
- store at room temperature
- see carton or tube crimp for lot number and expiration date

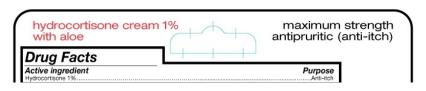
purified water/aqua/eau; glyceryl stearate and peg-100 stearate; c12-15 alkyl benzoate; isopropyl myristate; cetearyl alcohol and ceteareth-20; magnesium aluminum silicate; aloe barbadensis leaf juice; citric acid; polysorbate 80; sodium lauryl sulfate; propylene glycol,diazolidinyl urea, methlyparaben, propylparaben

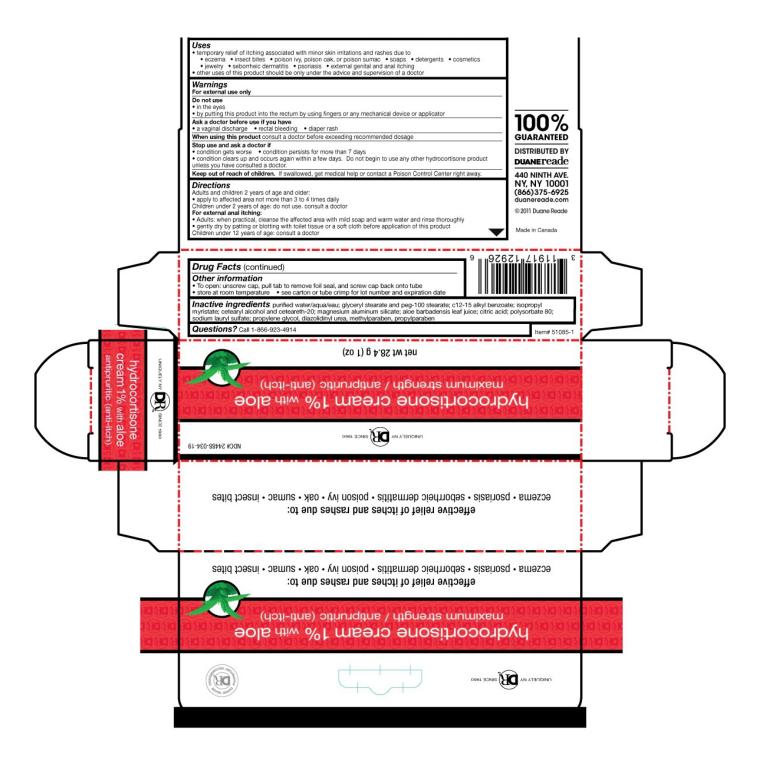
#### Questions?

Call 1-866-923-4914

Placeholder text







# **DUANE READE** hydrocortisone cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:24488-034

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	.284 g in 28.4 g		

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6 M3P6 4V0 NC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8 C7HI9 T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:24488-034-19	1 in 1 CARTON				
1	28.4 g in 1 TUBE				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	03/21/2011			

# Labeler - Duane Reade (961956229)

# Registrant - Creation's Garden Natural Products (961956229)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Creation's Garden Natural Products		961956229	manufacture	

Revised: 3/2011 Duane Reade