# REXALL ANTI ITCH MAXIMUM STRENGTH RELIEF- hydrocortisone cream Dolgencorp, LLC

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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### **Dolgencorp, LLC Anti-Itch Cream Drug Facts**

# Active ingredient

Hydrocortisone 1%

# Purpose

Anti-itch

#### Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
- eczema
- psoriasis
- poison ivy, oak, sumac
- insect bites
- detergents
- jewelry
- cosmetics
- soaps
- seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

# **Warnings**

For external use only

#### Do not use

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

#### When using this product

- avoid contact with the eyes
- do not use more than directed unless told to do so 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, and do not begin use of any other hydrocortisone product unless you have asked a doctor

rectal bleeding occurs

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center 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: do not use, ask a doctor
- for external anal and genital itching, adults:
- when practical, clean 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 applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

#### Other information

• store at 20°-25°C (68°-77°F)

#### **Inactive ingredients**

aloe barbadensis leaf juice, avena sativa (oat) kernel extract, benzyl alcohol, butylated hydroxytoluene, cetostearyl alcohol, cetyl alcohol, chamomilla recutita (matricaria) flower extract, diazolidinyl urea, dimethicone, distearyldimonium chloride, edetate disodium, glycerin, glyceryl monostearate, hydrolyzed collagen, hydrolyzed elastin, hydrolyzed jojoba esters, jojoba esters, magnesium ascorbyl phosphate, menthyl lactate, methyl gluceth-20, methylparaben, petrolatum, polysorbate 60, potassium hydroxide, PPG-12/SMDI copolymer, propylparaben, purified water, retinyl palmitate, stearamidopropyl PG-dimonium chloride phosphate, steareth-2, steareth-21, stearyl alcohol, tocopheryl acetate

# **Principal Display Panel**

For relief of

Dry, Itchy skin

Rashes

Insect bites

Eczema & Psoriasis

Inflammation, irritation & redness

MAXIMUM STRENGTH RELIEF

Anti-Itch Cream

Intensive Healing Formula

with Antioxidants, chamomile & aloe

24 Hour Clinically Proven to Moisturize 24 Hours 1% HYDROCORTISONE NET WT 1 0Z (28 g)





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- 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, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

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

#### Drug Facts (continued)

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#### REXALL ANTI ITCH MAXIMUM STRENGTH RELIEF

hydrocortisone cream

#### **Product Information**

HUMAN OTC DRUG LABEL Product Type Item Code (Source) NDC:55910-225

TOPICAL Route of Administration **DEA Schedule** 

#### **Active Ingredient/Active Moiety**

**Ingredient Name Basis of Strength** Strength **HYDROCORTISONE** (HYDROCORTISONE) HYDROCORTISONE 1 g in 100 g

# **Inactive Ingredients**

**Ingredient Name** Strength ALOE VERA LEAF OAT

BENZYL ALCOHOL

BUTYLATED HYDRO XYTO LUENE

CETOSTEARYL ALCOHOL

CETYL ALCOHOL

**CHAMOMILE** 

DIAZOLIDINYL UREA

**DIMETHICO NE** 

DISTEARYLDIMONIUM CHLORIDE

**EDETATE DISODIUM** 

GLYCERIN	
GLYCERYL MONOSTEARATE	
HYDROLYZED JOJOBA ESTERS (ACID FORM)	
MAGNESIUM ASCORBYL PHO SPHATE	
MENTHYL LACTATE, (-)-	
METHYL GLUCETH-20	
METHYLPARABEN	
PETROLATUM	
POLYSORBATE 60	
PO TASSIUM HYDRO XIDE	
PROPYLPARABEN	
WATER	
VITAMIN A PALMITATE	
STEARETH-2	
STEARETH-21	
STEARYL ALCOHOL	

Product Characteristics				
Color	WHITE (Off white)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

F	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55910-225-64	1 in 1 CARTON				
1		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	08/31/2010				

# Labeler - Dolgencorp, LLC (068331990)

Revised: 12/2013 Dolgencorp, LLC