

## **REXALL ANTI ITCH MAXIMUM STRENGTH RELIEF- hydrocortisone cream Dolgenercorp, 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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### **Dolgenercorp, 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

### **Questions or comments?**

**1-866-4-REXALL**

## **Principal Display Panel**

Since 1903

Rexall®

MAXIMUM STRENGTH RELIEF

Anti-Itch Cream

Intensive Healing Formula with Antioxidants, chamomile & aloe

1% HYDROCORTISONE

For relief of

- Dry, itchy skin
- Rashes
- Insect bites
- Eczema & Psoriasis
- Inflammation, irritation & redness

24 HOUR

NET WT 1 OZ (28g)

Clinically Proven to Moisturize 24 Hours



## REXALL ANTI ITCH MAXIMUM STRENGTH RELIEF

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55910-225
<b>Route of Administration</b>	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
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<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>OAT</b> (UNII: Z6J799EAJK)
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>CETYL ALCOHOL</b> (UNII: 936JT6JCN)
<b>CHAMOMILE</b> (UNII: FGL3685T2X)
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>DISTEARYLDIMONIUM CHLORIDE</b> (UNII: OM9573ZX3X)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>HYDROLYZED JOJOBA ESTERS (ACID FORM)</b> (UNII: UDR641JW8W)
<b>MAGNESIUM ASCORBYL PHOSPHATE</b> (UNII: OR822556M5)
<b>MENTHYL LACTATE, (-)-</b> (UNII: 2BF9E65L7I)
<b>METHYL GLUCETH-20</b> (UNII: J3QD0LD11P)
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)
<b>STEARETH-2</b> (UNII: V56DFE46J5)
<b>STEARETH-21</b> (UNII: 53J3F32P58)
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)
<b>STEARAMIDOPROPYL PROPYLENE GLYCOL-DIMONIUM CHLORIDE PHOSPHATE</b> (UNII: W6000VEI5Y)
<b>PPG-12/SMDI COPOLYMER</b> (UNII: 1BK9DDD24E)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>HYDROLYZED BOVINE ELASTIN (BASE; 1000 MW)</b> (UNII: ZR28QKN0WT)

### Product Characteristics

<b>Color</b>	WHITE (Off white)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-225-64	1 in 1 CARTON	08/31/2010	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	08/31/2010	

**Labeler** - Dolgencorp, LLC (068331990)

Revised: 3/2022

Dolgencorp, LLC