

## **HYDROCORTISONE- hydrocortisone cream**

### **H E B**

*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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### **HEB 1% Hydrocortisone 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**

- in the genital area 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 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 (1-800-222-1222).

**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, consult 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: consult a doctor

**Other information**

- store at 20-25°C (68-77°F)

**Inactive ingredients**

water, cetearyl alcohol, cetareth-20, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, aloe barbadensis leaf juice

**Questions or comments?**

**1-800-719-9260**

**Principal Display Panel**

Compare to active ingredient in Cortizone-10®

Maximum Strength

1% Hydrocortisone Cream

ANTI-ITCH CREAM

Plus Soothing Aloe

Maximum Strength

1% Hydrocortisone Cream

ANTI-ITCH CREAM

NET WT. 1 OZ (28g)

Plus Soothing Aloe



## HYDROCORTISONE

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-319
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<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**

<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:37808-319-64	1 in 1 CARTON	09/11/2015	
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	09/11/2015	

**Labeler - HEB (007924756)**

Revised: 11/2019

HEB