

**ANTI ITCH- hydrocortisone cream**  
**Meijer Distribution 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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**Meijer Distribution, Inc. 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**

- 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**

MAXIMUM STRENGTH

anti-itch cream

Hydrocortisone 1%

DOCTOR RECOMMENDED #1 anti-itch active ingredient

Relieves Itch Fast | With Soothing Aloe

INSECT BITES | POISON IVY | ECZEMA & PSORIASIS

Compare to Cortizone-10<sup>®</sup>

active ingredient

MAXIMUM STRENGTH

anti-itch cream

Hydrocortisone 1%

NET WT 2 OZ (56 g)

Relieves Itch Fast | With Soothing Aloe

INSECT BITES | POISON IVY | ECZEMA & PSORIASIS



Drug Facts		Drug Facts (continued)	
<b>Active ingredient</b> Hydrocortisone 1%	<b>Purpose</b> Anti-itch	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).	
<b>Uses</b> <ul style="list-style-type: none"> <li>■ temporarily relieves itching associated with mild or skin irritations, inflammation, and rashes due to:               <ul style="list-style-type: none"> <li>■ eczema</li> <li>■ psoriasis</li> <li>■ poison ivy, oak, sumac</li> <li>■ insect bites</li> <li>■ dermatitis</li> <li>■ jewelry</li> <li>■ contact dermatitis</li> <li>■ sunburn</li> <li>■ hemorrhoids</li> <li>■ soaps</li> <li>■ severe allergic reactions</li> </ul> </li> <li>■ temporarily relieves external anal and genital itching</li> <li>■ other uses of this product should only be under the advice and supervision of a doctor</li> </ul>	<b>Directions</b> <ul style="list-style-type: none"> <li>■ for itching of skin irritation, inflammation, and rashes:               <ul style="list-style-type: none"> <li>■ adults and children 2 years of age and older: apply to affected area no more than 3 to 4 times daily</li> <li>■ children under 2 years of age: do not use, consult a doctor</li> </ul> </li> <li>■ for external anal and genital itching, add to:               <ul style="list-style-type: none"> <li>■ when practical, clean the affected area with mild soap and warm water and rinse thoroughly</li> <li>■ gently dry by patting or blotting with toilet tissue or a soft cloth before applying</li> <li>■ apply to affected area no more than 3 to 4 times daily</li> <li>■ children under 12 years of age: consult a doctor</li> </ul> </li> </ul>		
<b>Warnings</b> For external use only Do not use <ul style="list-style-type: none"> <li>■ in the genital area if you have a vaginal discharge. Consult a doctor.</li> <li>■ for the treatment of diaper rash. Consult a doctor.</li> </ul> When using this product <ul style="list-style-type: none"> <li>■ avoid contact with eyes</li> <li>■ do not use more than directed unless told to do so by a doctor</li> <li>■ do not put directly in the rectum by using finger or any mechanical device or applicator</li> </ul> Stop use and ask a doctor if <ul style="list-style-type: none"> <li>■ condition worsens, symptoms persist for more than 7 days or disappear and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor</li> <li>■ rectal bleeding occurs</li> </ul>	<b>Other information</b> <ul style="list-style-type: none"> <li>■ store at 20-25°C (68-77°F)</li> </ul> <b>Inactive ingredients</b> water, cetaryl alcohol, ceteareth-20, cetyl palmitate, glycerin, isopropyl myristate, isobutyl alcohol, parabens, polyethylene glycol, propylparaben, sodium hydroxide, xanthan gum, and zinc oxide.		
<b>Questions or comments?</b> 1-800-719-9260		*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Cortizone-10®. **Of U.S. Physicians surveyed by an independent market research firm.	

## ANTI ITCH

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79481-0319
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISOPROPYL MYRISTATE</b> (UNII: ORE8K4LNJS)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISOSTEARYL NEOPENTANOATE</b> (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:79481-0319-0	1 in 1 CARTON	03/23/2021	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:79481-0319-1	1 in 1 CARTON	03/25/2021	
2		56 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	03/23/2021	

**Labeler** - Meijer Distribution Inc (006959555)

Revised: 11/2021

Meijer Distribution Inc