

ANTI ITCH- hydrocortisone cream

Rite Aid Corporation

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.

Rite Aid Corporation 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: ask 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 the active ingredient of Cortizone – 10[®] Creme

MAXIMUM STRENGTH

anti-itch cream

relieves itch fast

temporarily relieves skin irritation;

inflammation & redness; rashes;

insect bites; eczema & psoriasis

1% hydrocortisone

with soothing aloe

NET WT 1 OZ (28 g)



<p>Drug Facts</p> <p>Active ingredient Hydrocortisone 1%..... Purpose Anti-itch</p>		<p>Drug Facts (continued)</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).</p>
<p>Uses</p> <ul style="list-style-type: none"> temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: <ul style="list-style-type: none"> 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 		<p>Directions</p> <ul style="list-style-type: none"> for itching of skin irritation, inflammation, and rashes: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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
<p>Warnings</p> <p>For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> in the genital area if you have a vaginal discharge. Consult a doctor. for the treatment of diaper rash. Consult a doctor. <p>When using this product</p> <ul style="list-style-type: none"> avoid contact with 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 <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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 		<p>Other information</p> <ul style="list-style-type: none"> store at 20-25°C (68-77°F) <p>Inactive ingredients water, cetearyl alcohol, ceteareth-20, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopenantolate, methylparaben, aloe barbadensis leaf juice</p> <p>Questions or comments? 1-800-719-9260</p> <p><small>*This product is not manufactured or distributed by Chattem, Inc., distributor of Cortizone-10® Creme.</small></p>

CODE AREA

ANTI ITCH
hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0499
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
ISO STEARYL NEOPENTANOATE (UNII: 411THY156Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0499-2	1 in 1 CARTON	09/11/2013	
1		56 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11822-0499-1	1 in 1 CARTON	09/11/2013	
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:11822-0499-3	2 in 1 CARTON	09/11/2013	
3		56 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/11/2013	

Labeler - Rite Aid Corporation (014578892)