

HARRIS TEETER ANTI-ITCH INTENSIVE HEALING- hydrocortisone cream

Harris Teeter

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.

Active ingredient

Purpose

Hydrocortisone 1%.....Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to:
 - eczema
 - insect bites
 - cosmetics
 - psoriasis
 - detergents
 - soaps
 - poison ivy, oak, sumac
 - jewelry
 - 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 pull 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: 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 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 room temperature 20°-25°C (68°-77°F)
- lot no. & exp. date: see box or see crimp of tube

Inactive ingredients

alpha-tocopherol acetate, ascorbig acid, butylated hydroxtoluene, ceteth-20, cetyl alcohol, chamomile flower oil, decolorized aloe vera leaf,

methylparaben, mineral oil, propylene glycol, propylparaben, sodium hydroxide, sorbitan monostearate, stearyl alcohol, vitamin A palmitate,

water

Distributed by:

Harris Teeter, LLC

Matthews, NC 28105

Made in Korea



Maximum Strength

Anti-Itch Intensive Healing 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

Drug Facts (continued)

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: 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 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 room temperature 20°-25°C (68°-77°F)
- lot no. & exp. date: see box or see crimp of tube

Inactive ingredients alpha-tocopherol acetate, ascorbic acid, butylated hydroxytoluene, ceteth-20, cetyl alcohol, chamomile flower oil, decolorized aloe vera leaf, methylparaben, mineral oil, propylene glycol, propylparaben, sodium hydroxide, sorbitan monostearate, stearyl alcohol, vitamin A palmitate, water

Questions or comments? Call 1-800-814-8028

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Cortizone-10® Intensive Healing Creme.

Lot & Exp.



01-17-2017 TK

Support your local schools. Together in Education! Details available at any Harris Teeter or harrisiteer.com.

PROUDLY DISTRIBUTED BY: HARRIS TEETER, LLC MATTHEWS, NC 28105 MADE IN KOREA **yourPledge Guarantee.** 1-800-432-6111 or harrisiteer.com

NET WT 1 OZ (28 g)



Temporary Relief From: Rashes & Redness, Dry or Itchy Skin, Inflammation & Irritation, Eczema & Psoriasis
Hydrocortisone 1% | with Chamomile & Antioxidants, Vitamins A, C & E

Anti-Itch Intensive Healing Cream



Temporary Relief From: Rashes & Redness, Dry or Itchy Skin, Inflammation & Irritation, Eczema & Psoriasis
Hydrocortisone 1% | with Chamomile & Antioxidants, Vitamins A, C & E

Anti-Itch Intensive Healing Cream



NET WT 1 OZ (28 g)



Temporary Relief From: Rashes & Redness, Dry or Itchy Skin, Inflammation & Irritation, Eczema & Psoriasis
Hydrocortisone 1% | with Chamomile & Antioxidants, Vitamins A, C & E

Anti-Itch Intensive Healing Cream

Compare to Cortizone-10® Intensive Healing Creme active ingredient*

Maximum Strength



HARRIS TEETER ANTI-ITCH INTENSIVE HEALING

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-404
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
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETETH-20 (UNII: I835H2IHHX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC10H)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72036-404-28	1 in 1 CARTON	04/20/2017	
1		28 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	04/20/2017	

Labeler - Harris Teeter (047279351)

