

HYDROCORTISONE- anti-pruritic cream
Cardinal Health

CR-1139 Hydrocortisone Cream USP 1% NDC 70000-0485-1

Active Ingredient

Hydrocortisone USP 1%

Purpose

Antipruritic (Anti-Itch)

Uses

- For temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and for external genital, feminine, and anal itching.
- Other uses of this product should only be under the advice and supervision of a doctor.

Warnings

For external use only

If pregnant or breast-feeding,

ask a health professional before use.

Do not use

- in the eyes
- for diaper rash
- for external genital or feminine itching if you have a vaginal discharge
- more than the recommended daily dosage unless directed by a doctor
- this product in the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens or if symptoms persist more than 7 days or clear up and occur again within a few days. Do not continue to use this or any other hydrocortisone product for longer than 7 days.
- bleeding occurs near anus when used for anal itching

If swallowed, get medical help or contact a Poison Control Center (1-888-222-1222) right away.

Directions

- **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:** consult a doctor.
- When used for anal itching, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry, patting or blotting with bathroom tissue or soft cloth before applying. **Children under 12:** consult a doctor before using for anal itching.

Other Information

Store at room temperature

Inactive Ingredients

Cetostearyl Alcohol, Glyceryl Palmitostearate, Kathon, Petrolatum, Propylene Glycol, Stearic Acid, Tea Leaf, Water

Questions and Comments?

1-888-396-2739

Label PDP

NDC 70000-0485-1

LEADER²

Maximum Strength Hydrocortisone Cream

Hydrocortisone, USP 1% | Anti-Itch Cream

LEADER²

Maximum Strength Hydrocortisone Cream

Hydrocortisone, USP 1% | Anti-Itch Cream

COMPARE TO CORTIZONE 10[®] MAXIMUM STRENGTH ANTI-ITCH CREAM active ingredient*

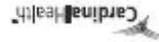
NET WT 1 OZ (28.4 g)



LOT NO. EXP. R. 07454 R. 01/19

Return to place of purchase if not satisfied.
100% Money Back Guarantee
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<p>Drug Facts</p> <p>Active ingredient Hydrocortisone USP 1% Antipruritic (Anti-Itch)</p> <p>Purpose condition worsens or if symptoms persist more than 7 days or deep up and occur again within a few days. Do not continue to use this or any other hydrocortisone product for longer than 7 days.</p> <p>bleeding occurs near anus when used for anal itching</p> <p>Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center (1-888-232-1222) right away.</p> <p>Directions</p> <p>Adults and children 2 years of age and older: apply to affected area no more than 3 to 4 times a day. Children under 2 years of age: consult a doctor.</p> <p>When used for anal itching, cleanse the affected area with mild soap and warm water and use to dry. Gently dry. Gently pat or blot with a clean towel. Use for anal itching.</p> <p>Warnings</p> <p>Do not use for external use only.</p> <p>If pregnant or breastfeeding, ask a health professional before use.</p> <p>Do not use</p> <ul style="list-style-type: none"> in the eyes for diaper rash for external genital or feminine itching if you have a vaginal discharge more than the recommended daily dosage unless directed by a doctor with this product in the rectum by using fingeres or any mechanical device applicator <p>Uses</p> <ul style="list-style-type: none"> For temporary relief of itching associated with minor skin irritations, inflammation, or rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and for external genital, feminine, and anal itching. Other uses of this product should only be under the advice and supervision of a doctor. <p>Warnings</p> <p>For external use only.</p> <p>If pregnant or breastfeeding, ask a health professional before use.</p> <p>Do not use</p> <ul style="list-style-type: none"> in the eyes for diaper rash for external genital or feminine itching if you have a vaginal discharge more than the recommended daily dosage unless directed by a doctor with this product in the rectum by using fingeres or any mechanical device applicator <p>Drug Facts</p> <p>Active ingredient Hydrocortisone USP 1% Antipruritic (Anti-Itch)</p> <p>Purpose condition worsens or if symptoms persist more than 7 days or deep up and occur again within a few days. Do not continue to use this or any other hydrocortisone product for longer than 7 days.</p> <p>bleeding occurs near anus when used for anal itching</p> <p>Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center (1-888-232-1222) right away.</p> <p>Directions</p> <p>Adults and children 2 years of age and older: apply to affected area no more than 3 to 4 times a day. Children under 2 years of age: consult a doctor.</p> <p>When used for anal itching, cleanse the affected area with mild soap and warm water and use to dry. Gently dry. Gently pat or blot with a clean towel. Use for anal itching.</p> <p>Warnings</p> <p>Do not use for external use only.</p> <p>If pregnant or breastfeeding, ask a health professional before use.</p> <p>Do not use</p> <ul style="list-style-type: none"> in the eyes for diaper rash for external genital or feminine itching if you have a vaginal discharge more than the recommended daily dosage unless directed by a doctor with this product in the rectum by using fingeres or any mechanical device applicator <p>Uses</p> <ul style="list-style-type: none"> For temporary relief of itching associated with minor skin irritations, inflammation, or rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis and for external genital, feminine, and anal itching. Other uses of this product should only be under the advice and supervision of a doctor. <p>Warnings</p> <p>For external use only.</p> <p>If pregnant or breastfeeding, ask a health professional before use.</p> <p>Do not use</p> <ul style="list-style-type: none"> in the eyes for diaper rash for external genital or feminine itching if you have a vaginal discharge more than the recommended daily dosage unless directed by a doctor with this product in the rectum by using fingeres or any mechanical device applicator <p>Questions and Comments? 1-888-396-2739</p> <p>Keep this carton for complete drug facts and information.</p>	<p>Keep this carton for complete drug facts and information.</p> <p>Questions and Comments? 1-888-396-2739</p> <p>Inactive ingredients Cetostearyl Alcohol, Glycerin Mono Stearate SE, Kathon CG, Propylene Glycol, Purified Water, Stearic Acid, Triethanolamine, White Soft Paraffin</p> <p>Other information Store at room temperature</p>
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HYDROCORTISONE

anti-pruritic cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0485
Route of Administration	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
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 15O9QS218W)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0485-1	72 in 1 CASE	01/18/2019	
1		1 in 1 BOX		
1		28.4 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 Drug	M017	01/18/2019	

Labeler - Cardinal Health (063997360)