

**LEADER HYDROCORTISONE WITH ALOE- hydrocortisone cream
CARDINAL HEALTH**

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

for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to:

- eczema
- seborrheic dermatitis
- psoriasis
- insect bites
- poison ivy, oak, sumac
- soaps
- detergents
- cosmetics
- jewelry
- external genital, feminine and anal itching.

Other uses or the use of the product for more than 7 days should be undertaken only under the advice and supervision of a doctor

Warnings

- for external use only
- avoid contact with eyes

Stop using this product and ask a doctor

- if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- before you begin using any other hydrocortisone product

Do not use this product and ask a doctor

- if you have a vaginal discharge
- before treating diaper rash
- before using on children under 2 years of age

Keep this and all drugs out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Before using any medication, read all label directions. Keep this carton. It contains important information.

Directions

- for 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 itching users

- adults: when practical, cleanse 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 application of this product.

- children under 12 years of age: consult a doctor

Other information

- store at room temperature
- Lot No. and Exp. Date: see box or see crimp of tube

Inactive ingredients

aloe vera gel, butylated hydroxytoluene, cetanol, liquid paraffin, methylparaben, polyoxyethylene cethylether, propylene glycol, propylparaben,

purified water, psorbitan monostearate, stearyl alcohol

DISTRIBUTED BY

CARDINAL HEALTH, DUBLIN, OHIO 43017

www.myleader.com

1-800-200-6313

Made in Korea



Compare to Cortizone-10® active ingredient

MAXIMUM STRENGTH with ALOE

1% Hydrocortisone Cream

ANTI-ITCH CREAM

Maximum strength cream relieves itches, rashes and skin irritations!
• eczema • poison ivy, oak and sumac • insect bites • psoriasis • dermatitis

NDC 37205-272-10



MAXIMUM STRENGTH with ALOE

1% Hydrocortisone Cream

ANTI-ITCH CREAM

NET WT 1 OZ (28g)



96295 22120
Made in Korea
DISTRIBUTOR: CAROLINA HEALTH, DUBLIN, OHIO 43017
1-800-200-6313
www.leader.com
NIN 12/21/09

Drug Facts (cont'd.)
Other information ■ store at room temperature
■ Lot No. & Exp. Date: see box or see crimp of tube
Inactive ingredients aloe vera gel, butylated hydroxytoluene, cetanol, liquid paraffin, methylparaben, polyoxyethylene cetyl ether, propylene glycol, propylparaben, purified water, sorbitan monostearate, stearyl alcohol
Questions or comments? 1-800-814-8028

Drug Facts
Active ingredient Hydrocortisone 1%
Purpose Anti-itch
Uses for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to: ■ eczema ■ seborrheic dermatitis ■ psoriasis ■ insect bites ■ poison ivy, oak, sumac ■ soaps ■ detergents ■ cosmetics ■ jewelry ■ external genital, feminine and anal itching.
Other uses of this product should be only under the advice and supervision of a doctor.
Warnings
■ for external use only ■ avoid contact with eyes
Stop using this product and ask a doctor
■ if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
■ before you begin using any other hydrocortisone product
Do not use this product and ask a doctor
■ if you have vaginal discharge ■ before treating diaper rash
■ before using on children under 2 years of age
For external anal itching users:
■ do not exceed the recommended daily dosage unless directed by a doctor
■ in case of bleeding, consult a doctor promptly ■ do not put this product into rectum by using fingers or any mechanical device or applicator
■ children under 12 years of age: consult a doctor
Keep this and all drugs out of the reach of children.
If swallowed, get medical help or contact a Poison Control Center right away.
Before using any medication, read all label directions. Keep this carton. It contains important information.
Directions
■ adults and children 2 years of age and older: apply to affected area no more than 3 to 4 times daily
■ children under 2 years of age: do not use, consult a doctor
For external anal itching users
■ adults: when practical, cleanse 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 application of this product
■ children under 12 years of age: consult a doctor
* This product is not manufactured or distributed by Chateam, Inc., owner of the registered trademark Cortizone-10®.

LOT & EXP.

22120-11-BX-R1

LEADER HYDROCORTISONE WITH ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-272
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PARAFFIN (UNII: I9O0E3H2ZE)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-272-10	1 in 1 CARTON	10/11/2016	
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	03/01/2012	

Labeler - CARDINAL HEALTH (097537435)

Revised: 7/2017

CARDINAL HEALTH