

LEADER HYDROCORTISONE WITH ALOE- hydrocortisone cream

LEADER

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.

LEADER™ HYDROCORTISONE CREAM 1% WITH ALOE

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Antipruritic (anti-itch)

Uses

- for the 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
- and for external anal and genital itching.

Warnings

For external use only.

Avoid contact with eyes.

Do not use

- if you have a vaginal discharge. Consult a doctor.

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put 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 occurs again within a few days
- bleeding occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.

Directions

For itching associated with minor skin irritations, 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: Consult a doctor

For external anal and genital itching:

Adults and children 12 years of age and older:

- when practical, cleanse the affected area with mild soap or warm water and rinse thoroughly or by patting or blotting with an appropriate cleansing pad
- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- 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 15 to 30°C (59 to 86°F).

Tamper Evident: DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, carbomer, cetyl alcohol, DMDM hydantoin, glyceryl stearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, propylparaben, purified water, stearic acid, triethanolamine, trisodium EDTA

Questions or comments?

866-323-0107 or www.natureplex.com

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

NDC 70000-0543-1

LEADER™

Maximum Strength

Hydrocortisone Cream
with Aloe

Hydrocortisone, 1% | Anti-Itch

COMPARE TO

CORTIZONE-10®
WITH ALOE
MAXIMUM STRENGTH
active ingredient*

100% Money Back Guarantee

Fast Itch Relief
Relief in a Soothing Cream

- Eczema • Insect Bites • Psoriasis
- Poison Ivy, Oak & Sumac • Seborrheic Dermatitis
- Soaps • And More

NET WT 1 OZ (28 g)

LEADER²

NDC 70000-0565-1

Maximum Strength
Hydrocortisone Cream
 with Aloe
 Hydrocortisone, 1% | Anti-Itch

PL31310B
 V01

Maximum Strength
Hydrocortisone
 Cream with Aloe

LEADER²

Fast Itch Relief
Relief in a Soothing Cream

- Eczema • Insect Bites • Psoriasis
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COMPARE TO
CORTIZONE-10[®]
WITH ALOE
MAXIMUM STRENGTH
 active ingredient*

100% Money Back Guarantee

NET WT 1 OZ (28 g)



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 DUBLIN, OHIO 43017
 www.myleader.com
 1-800-200-6315
 Essential to Care[™] since 1979

*This product is not manufactured or distributed by Chatter, Inc., the distributor of Cortizone-10[®] with Aloe Maximum Strength.
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All LEADER² Brand Products Have A
100% Money Back Guarantee

Return to place of purchase if not satisfied.

CIN 5579768 REV. 1/20



Drug Facts	Drug Facts (continued)
Active ingredient Hydrocortisone 1% (anti-itch)	Directions For itching associated with minor skin irritations, inflammation, and rashes: Adults and children 2 years of age and older: • apply to affected areas no more than 3 to 4 times daily Children under 2 years of age: Consult a doctor For eczema and allergic dermatitis: Adults and children 12 years of age and older: • when prescribed, cleanse the affected area with mild soap or water and dry thoroughly • apply to affected area no more than 3 to 4 times daily Children under 12 years of age: Consult a doctor
Uses For the 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, powders, and perfumes.	Other information Store at 20° to 25°C (68° to 77°F). Tamper resistant sealant. DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.
Warnings For external use only. Do not use if you have a vaginal discharge. Consult a doctor. When using this product, do not exceed the recommended daily dosage unless directed by a doctor. Do not apply to the rectum by using fingers or any medicinal 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. If pregnant or breastfeeding, ask a health professional before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. 800-222-1222.	Inactive ingredients Aloe barbadensis leaf juice, carbomer, castor alcohol, DMDM hydantoin, glyceryl sebacate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, propylparaben, purified water, sebacic acid, tetrahydrofurfuryl alcohol, triiodium EDTA.
Questions or comments? 866-23-0107 or www.natureplac.com	

Maximum Strength
Hydrocortisone Cream with Aloe

LEADER²

LEADER HYDROCORTISONE WITH ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0543
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE TRISODIUM (UNII: 420IP921MB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0543-1	1 in 1 CARTON	01/17/2020	
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	01/17/2020	

Labeler - LEADER (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(70000-0543)

Revised: 6/2021

LEADER