

CORTICOL-ALOE- hydrocortisone cream
MENPER DISTRIBUTORS INC.

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

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 extranal 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.

Directions

- for itchin 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 thouroughly
- 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

Inactive ingredients

aloe barbadensis leaf juice, beeswax, clacium acetate, cetearyl alcohol, glycerin, maltodextrin, mehtylparaben, mineral oil, propylparaben, sodium cetearyl sulfate, sodium lauryl sulfate, water, white petrolatum

Questions

www.menperdistributors.com or 1-800-560-5223 M-F 9 am - 4 pm EST

Corticol-Aloe

1% Hydrocortisone

ANTI-ITCH
Creme

- For the relief of:
- ITCHING
 - RASHES
 - SKIN IRRITATIONS
 - INFLAMMATION
- Net wt 1 oz (28 g)



with Soothing
ALOE!



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Distributed by:
Menper Distributors, Inc.
11421 N.W. 107 Street Suite #24
Miami, FL 33178
www.menperdistributors.com



Drug Facts	Hydrocortisone 1% Anti-itch
Active ingredient	Hydrocortisone 1%
Purpose	Anti-itch
Uses	relieves itching associated with minor skin irritations, inflammation, and rashes due to: ■ temporary relief of external anal and genital itching ■ other uses of this product should only be under the advice and supervision of a doctor ■ eczema ■ psoriasis ■ poison ivy, oak, sumac ■ insect bites ■ detergents ■ jewelry ■ cosmetics ■ soaps ■ sebhoric dermatitis
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 ■ do not put directly into the rectum by using fingers or any mechanical device or applicator ■ avoid contact with the eyes ■ do not use more than directed unless told to do so by a doctor 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 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
Inactive ingredients	aloe barbadensis leaf juice, beeswax, calcium acetate, cetaryl alcohol, glycerin, methylparaben, mineral oil, propylparaben, sodium cetaryl sulfate, sodium lauryl sulfate, water, white petrolatum.
Questions?	www.menperdistributors.com or 1-800-560-5223, M-F 9 am-4 pm EST

CORTICOL-ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-430
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
CALCIUM ACETATE (UNII: Y882YXF34X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KOOR)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-430-28	1 in 1 PACKAGE	07/01/2019	
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	07/01/2019	

Labeler - MENPER DISTRIBUTORS INC. (101947166)