

**GELMICIN HYDROCORTISONE WITH ALOE- hydrocortisone cream
United Exchange Corp.**

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.

Gelmicin Hydrocortisone Cream with Aloe 1.41 oz 64035 ZDP

Active ingredient Purpose

Hydrocortisone 1%.....Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
- eczema, psoriasis, jewelry, insect bites, soaps, cosmetics, detergents, seborrheic dermatitis, poison ivy, oak sumac
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advise 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.
- more than directed unless directed by a doctor

When using this product

- avoid contact with eyes
- 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

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 (1-800-222-1222) right away.

Directions

- before first use, remove or puncture seal under cap by using the tip of the cap
- for itching of skin irritation, inflammation, and rashes:
- adults and children 2 years 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

Other information

- store at room temperature 20-25°C (68-77°F)

Inactive ingredients

aloe vera leaf, aluminum sulfate octadecahydrate, calcium acetate monohydrate, cetostearyl alcohol, dextrin, light mineral oil, maltodextrin, methylparaben, petrolatum, propylene glycol, propylparaben, purified water, sodium cetearyl sulfate, sodium lauryl sulfate, white wax

Distributed by:

Gute Besserung Hauser

San Diego, CA 92154

Made in China



GELMICIN HYDROCORTISONE WITH ALOE
hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-035
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
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ALUMINIUM SULFATE OCTADECALHYDRATE (UNII: TCS9L00G8F)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WHITE WAX (UNII: 7G1J5DA97F)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CALCIUM ACETATE MONOHYDRATE (UNII: 7ZA48GIM5H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-035-40	1 in 1 CARTON	02/22/2021	
1		40 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	02/22/2021	

Labeler - United Exchange Corp. (840130579)

