HYDROCORTISONE- hydrocortisone lotion
AKRON PHARMA 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.

Hydrocortisone USP 1% Lotion

Drug Facts

Active Ingredient

Hydrocortisone 1% (Micronized)

Purpose

Antipruritic (Anti-itch)

Use

For the temporary relief of minor skin irritations, inflammations, itching and rashes caused by:

- insect bites
- eczema
- psoriasis
- soaps
- detergents
- cosmetics,
- jewelry,
- poison oak,
- poison sumac
- Other uses of this product should be undertaken only under the advice and supervision of a doctor.

Warnings

For external use only.

When using this product

Do not get into eyes. If contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if

- Condition worsens
- If symptoms persist for more than 7 days or clear up and occur again within a few days. Discontinue use of this product and do not begin use of any other hydrocortisone product unless you have consulted a doctor.
- Do no use for diaper rash. Consult a doctor.

Keep out of Reach of Children

Keep out of the reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Directions

- Shake will before using.
- For adults and children 2 years of age and older: Apply to affected area not more than 2 to 4 times daily.
- For children under 2 years of age: there is no recommended dosage except under the advice and supervision of a doctor.

Other Information

• Store away from excessive heat or cold. Shake well before using.

Inactive Ingredients

Purified Water, Glycerin, Cetyl Alcohol, Benzyl Alcohol, Sodium Lauryl Sulfate, Stearyl Alcohol, Aloevera, Xanthan Gum

Questions?

Please Call 1(877) 225-6999

Manufactured for:

Akron Pharma, Inc.
Fairfield, NJ 07004

Rev. 03/19

Manufactured in U.S.A

HYDROCORTISONE

hydrocortisone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71399-0120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0120-1	1 in 1 CARTON	05/17/2021	
1		120 mL in 1 BOTTLE; 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	05/17/2021	

Labeler - AKRON PHARMA INC (067878881)

Establishment

Name	Address	ID/FEI	Business Operations
SLV PHARMACEUTICALS LLC		081225162	manufacture(71399-0120)

Revised: 5/2021 AKRON PHARMA INC