

HYDROCORTISONE- hydrocortisone cream

Acme United 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.

Drug Facts

Active Ingredients

Hydrocortisone 1.0%

Purpose

Anti-itch

Uses

For temporary relief of itching associated with minor skin irritations, inflammation or rashes.

Other uses of product should be only under the advice of supervision of a doctor.

Warnings

For external use only

Do not use

- in eyes
- for treatment of dipper rash

Stop use, ask a doctor

- if condition worsens or lasts more than 7 days, or clears up and occurs again within a few days
- with use of other hydrocortisone products

Keep out of reach of children.

If ingested, contact a Poison Control Center right away

Directions

- apply to affected area not more than 3 to 5 times daily
- children under 2: as a doctor

Inactive Ingredients

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

Principal Display Panel - 0.9g Carton Label

18-012

MISC

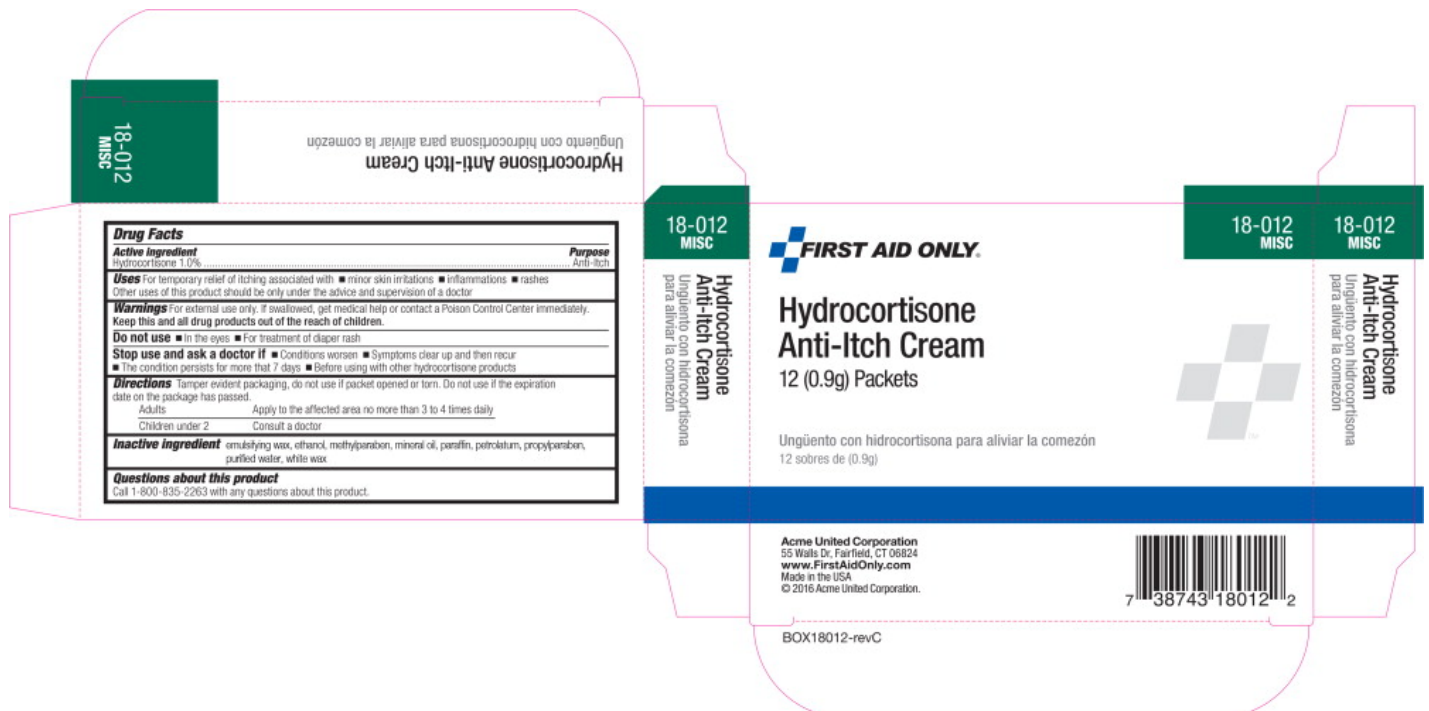
FIRST AID ONLY[®]

Hydrocortisone Anti-Itch Cream

12 (0.9g) Packets

Ungüento con hidrocortisona para aliviar la comezón

12 sobres de (0.9g)



Principal Display Panel - 0.9g Packet Label

Anti-Itch Cream

0.9g ($\frac{1}{32}$ oz)

FIRST AID ONLY®

www.FirstAidOnly.com

Fairfield, CT 06824

1.800.835.2263

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Anti-Itch Cream

0.9g (1/32 oz)



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810002-revA

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Uses For temporary relief of itching associated with minor skin irritations, inflammation or rashes. Other uses of product should be only under the advice and supervision of a doctor. ▶

Drug Facts (cont'd)

Warnings

For external use only

Do not use

■ in eyes ■ for treatment of diaper rash

Stop use, ask a doctor

■ if condition worsens or lasts more than 7 days, or clears up and occurs again within a few days

■ with use of other hydrocortisone products

Keep out of reach of children.

If ingested, contact a Poison Control Center right away

Directions ■ apply to affected area not more than 3 to 4 times daily ■ children under 2: ask a doctor

Inactive Ingredients

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-1132
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	

mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6H12BN9U)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
white wax (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-1132-02	12 in 1 CARTON		
1	NDC:0924-1132-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0924-1132-03	144 in 1 CARTON		
2	NDC:0924-1132-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0924-1132-04	25 in 1 CARTON		
3	NDC:0924-1132-01	0.9 g in 1 PACKET; 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	11/06/2015	

Labeler - Acme United Corp (001180207)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(0924-1132)