

**FIRST AID ONLY HYDROCORTISONE 1% ANTI-ITCH- hydrocortisone cream**  
**Acme United Corporation**

*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.*

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**First Aid Only Hydrocortisone 1% Anti-Itch Cream**

**ACTIVE INGREDIENT**

Hydrocortisone 1%

**PURPOSE**

Anti-Itch

**USES**

Uses ■ temporarily relieves itching associated with minor skin irritations and rashes  
■ other uses should be only under the advice and supervision of a doctor

**WARNINGS**

**For external use only.**

**Do not use**

for a diaper rash. Consult a doctor.

**When using this product**

- Avoid contact with the eyes
- Do not begin use of any other Hydrocortisone product unless you have asked a doctor

**Stop use and ask a doctor if**

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days

**Keep out of reach of children.** If swallowed get medical help or contact poison control (800-222-1222) right away.

**DIRECTIONS**

**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 Do not use, consult a doctor**

**OTHER INFORMATION**

- Store at 15° to 30°C (59° to 86°F)

**INACTIVE INGREDIENTS**

ceteth-20, cetostearyl alcohol, chlorocresol, liquid paraffin, propylene glycol, purified water, soft paraffin

**Questions 1.800.835.2263**

Carton image

<b>Drug Facts</b>	
<b>Active ingredient</b> Hydrocortisone 1%	<b>Purpose</b> Anti-Itch
<b>Uses</b> ■ temporarily relieves itching associated with minor skin irritations and rashes ■ other uses should be only under the advice and supervision of a doctor	
<b>Warnings</b> <b>For external use only.</b> <b>Do not use</b> for a diaper rash. Consult a doctor.	
<b>When using this product</b> ■ avoid contact with eyes ■ do not begin use of any other hydrocortisone product unless you've consulted a doctor	
<b>Stop use and ask a doctor if</b> ■ condition worsens or symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days	
<b>Keep out of reach of children.</b> If swallowed get medical help or contact poison control (800-222-1222) right away.	
<b>Directions</b> 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 Do not use, consult a doctor	
<b>Other information</b> Store at 15°-30°C (59°-86°F)	
<b>Inactive ingredients</b> ceteth-20, cetostearyl alcohol, chlorocresol, liquid paraffin, propylene glycol, purified water, white petrolatum	
<b>Questions</b> 1.800.835.2263	



Manufactured for:  
**Acme United Corporation**  
 1 Waterview Dr, Shelton, CT 06484  
[www.FirstAidOnly.com](http://www.FirstAidOnly.com)  
 Made in India  
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 G.U./DRUGS/G/28/1551



807711-revA

**FIRST AID ONLY HYDROCORTISONE 1% ANTI-ITCH**

hydrocortisone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0924-5633(NDC:50382-024)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
MINERAL OIL (UNII: T5L8T28FGP)	
CHLOROCRESOL (UNII: 36W53O7109)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

**PETROLATUM** (UNII: 4T6H12BN9U)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-5633-01	12 in 1 CARTON	08/05/2022	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0924-5633-00	0.9 g in 1 PACKET; Type 0: Not a Combination Product	08/05/2022	
3	NDC:0924-5633-02	25 in 1 CARTON	08/05/2022	
3		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	08/02/2012	

**Labeler** - Acme United Corporation (001180207)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corpoation		045924339	relabel(0924-5633) , repack(0924-5633)

### Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	repack(0924-5633) , relabel(0924-5633)

Revised: 8/2022

Acme United Corporation