# HYDROCORTISONE- hydrocortisone cream Acme United Corporation

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# First Aid Only Hydrocortisone 1% Anti-Itch Cream

**Drug Facts** 

## **Active Ingredient**

Hydrocortisone 1.0%

## **Purpose**

Anti-itch

#### Uses:

For temporary relief of itching associated with minor skin irritations and rashes.

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

# Warnings

# For external use only

- Do not use
- in eyes
- for diaper rash

# Stop use and ask a doctor if

- condition worsens or lasts for more than 7 days symptoms clear up and occur again within a few days
- you begin using other hydrocortisone products

## KEEP OUT OF REACH OF CHILDREN.

If swallowed, contact a Poison Control Center right away.

#### **Directions:**

Adults and children over 2 years of age

- apply to affected area not more than 3 to 4 times daily
- children under 2, consult a doctor

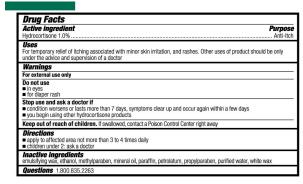
# **Inactive ingredients**

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum,

### Questions

1.800.835.2263

#### Box Label







Acme United Corporation 1 Waterview Dr, Shelton, CT 06484 www.FirstAidOnly.com Assembled in the USA with domestic & foreign components © 2023 Acme United Corporation.



806506-001-revA

## **HYDROCORTISONE**

hydrocortisone cream

Duad		Infauna	2122
Prod	luct	Inform	ation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0924-1133(NDC:61010-5800)

TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name

Basis of Strength

HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)

HYDROCORTISONE

10 mg in 1 g

# **Inactive Ingredients**

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: 1900E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
STEARETH-20 (UNII: LOQ8IK9E08)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-1133- 00	0.9 g in 1 POUCH; Type 0: Not a Combination Product	05/08/2023	
2	NDC:0924-1133- 01	10 in 1 BOX	05/08/2023	
2		0.9 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:0924-1133- 02	12 in 1 BOX	05/08/2023	
3		0.9 g in 1 POUCH; Type 0: Not a Combination Product		
4	NDC:0924-1133- 03	20 in 1 BOX	05/08/2023	
4		0.9 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:0924-1133- 04	25 in 1 BOX	05/08/2023	
5		0.9 g in 1 POUCH; Type 0: Not a Combination Product		
6	NDC:0924-1133- 05	100 in 1 BOX	05/08/2023	
6		0.9 g in 1 POUCH; Type 0: Not a Combination Product		
7	NDC:0924-1133- 06	144 in 1 BOX	05/08/2023	
7		0.9 g in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M017	05/08/2023			

# Labeler - Acme United Corporation (001180207)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Acme United Corporation		045924339	relabel(0924-1133) , repack(0924-1133)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Acme United Corporation		080119599	relabel(0924-1133) , repack(0924-1133)	