

HYDROCORTISONE- hydrocortisone cream
Acme United Corporation

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,

propylparaben, purified water, white wax

Questions

1.800.835.2263

Box Label

Drug Facts	
Active ingredient Hydrocortisone 1.0%	Purpose Anti-Itch
Uses For temporary relief of itching associated with minor skin irritation, 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 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 ■ 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	
Questions 1.800.835.2263	

90945
MISC

Hydrocortisone 1%
Anti-Itch Cream



**Hydrocortisone 1%
Anti-Itch Cream**

10 Packets 0.9g each

90945
MISC

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MISC



Hydrocortisone 1%
Anti-Itch Cream

Acme United Corporation
1 Waterview Dr, Shelton, CT 06484
www.FirstAidOnly.com
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domestic & foreign components
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806506-001-revA

HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0924-1133(NDC:61010-5800)
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 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)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
STEARETH-20 (UNII: L0Q8IK9E08)	

Packaging

#	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	Business Operations
Acme United Corporation		045924339	relabel(0924-1133) , repack(0924-1133)

Establishment

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