HYDROCORTISONE- 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.

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

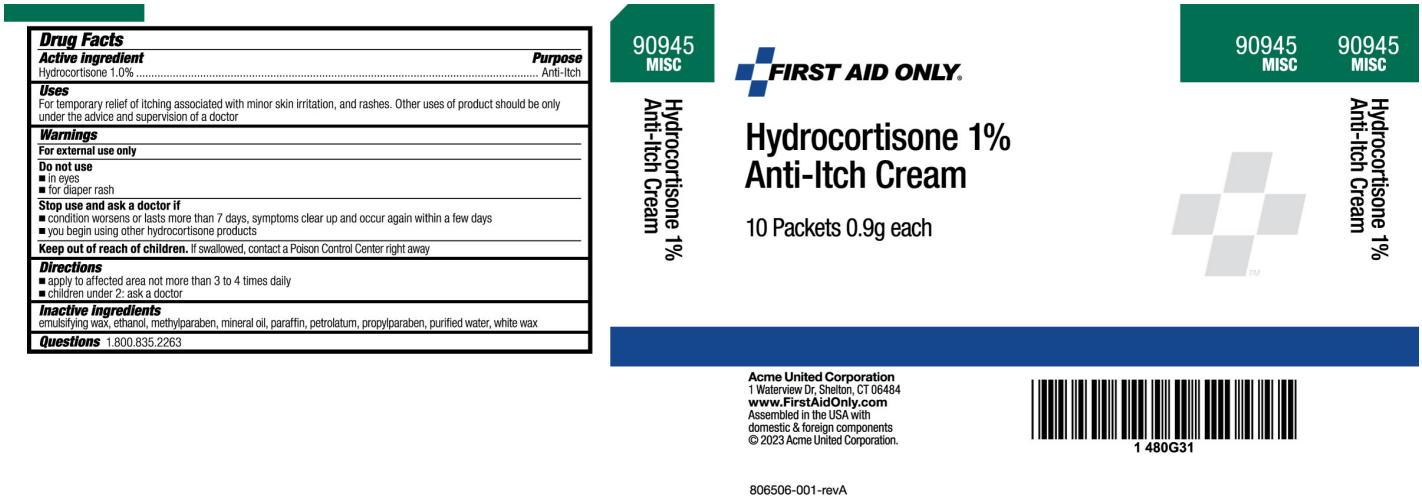
Inactive ingredients

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

Questions

1.800.835.2263

Box Label



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 not final	part348	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)