HYDROCORTISONE- anti-itch cream ointment
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

Active ingredient

Hydrocortisone acetate (equivalent to Hydrocortisone 1%)

Purpose

Anti-itch

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

Do not use ▪ in or near eyes

▪ for a diaper rash. Consult a doctor.

When using this product

- avoid contact with eyes
- do not begin use of any other hydrocortisone product unless you've consulted a doctor

Stop use and ask a doctor if

- 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 the 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; do not use, consult a doctor

Other information

- store at room temperature

Inactive ingredients

cetyl alcohol, citric acid, diazolidinyl urea, edetate disodium, glycerin, glyceryl monostearate,

methylparaben, mineral oil, polyethylene glycol, propylparaben, purified water, stearic acid, trolamine

Questions ?

1.800.835.2263

HYDROCORTISONE

anti-itch cream ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0924-5632(NDC:59898-800)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYETHYLENE GLYCOL 10000 (UNII: H57W405143)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0924-5632-03	20 in 1 CARTON	12/20/2019	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:0924-5632-04	25 in 1 CARTON	12/20/2019	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:0924-5632-01	10 in 1 CARTON	12/20/2019	
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:0924-5632-00	0.9 g in 1 PACKET; Type 0: Not a Combination Product	12/20/2019	
5	NDC:0924-5632-02	12 in 1 CARTON	12/20/2019	
5		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
6	NDC:0924-5632-05	60 in 1 CARTON	12/20/2019	
6		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
7	NDC:0924-5632-06	144 in 1 CARTON	12/20/2019	
7		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	12/20/2019	

Labeler - Acme United Corporation (001180207)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		045924339	relabel(0924-5632) , repack(0924-5632)

Establishment

Name	Address	ID/FEI	Business Operations
Acme United Corporation		080119599	relabel(0924-5632) , repack(0924-5632)

Revised: 12/2019 Acme United Corporation