HYDROCORTISONE- hydrocortisone acetate cream
HART Health

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.

HYDROCORTISONE CREAM

Active Ingredient (in each gram): Hydrocortisone Acetate 10mg (equivalent to Hydrocortisone 1%)

Purpose: anti-itch cream

Warnings: For external use only. Do not get in eyes

Allergy alert: A severe allergic reaction to insect bites or stings may require life support measures. In such cases, immediately clal 911 or your local emergency provider.

Do not use:
- in the eyes or over large portions of the body
- for the treatment of diaper rash
- with any other hydrocortisone product

Stop use and ask a doctor if:
- condition worsens
- condition lasts 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 a Poison Control Center right away. 1-800-222-1222

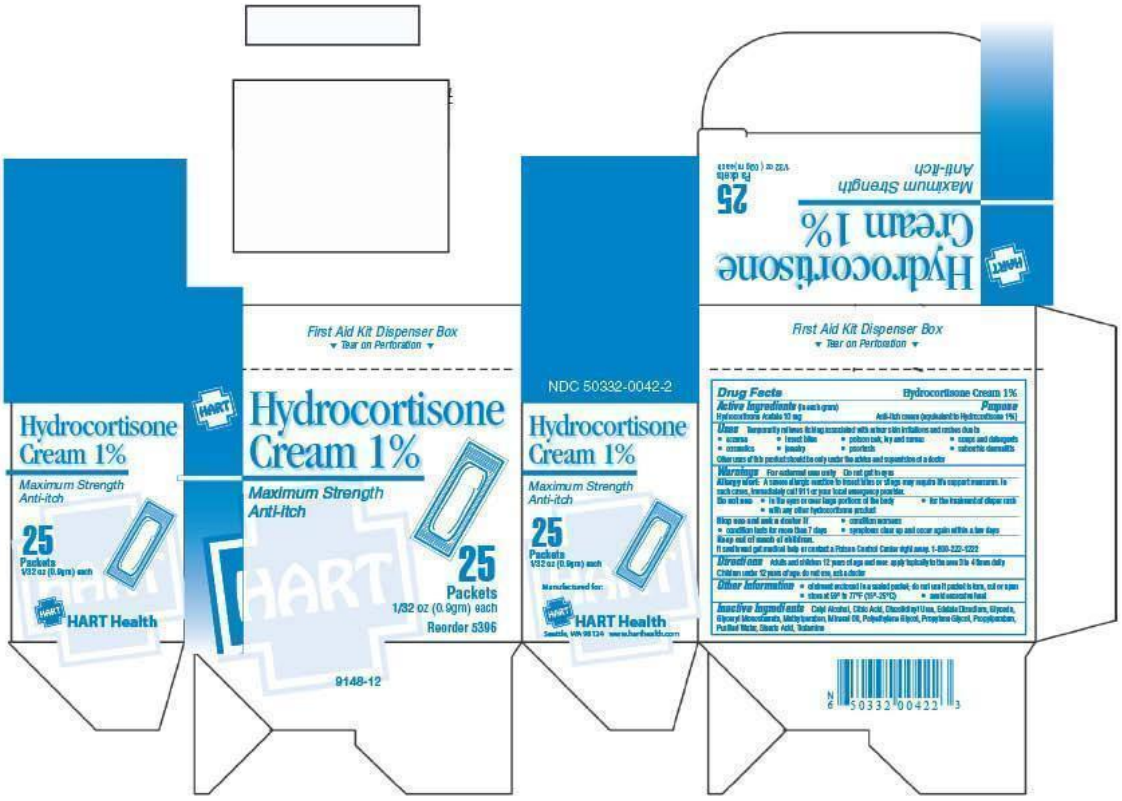
Directions:

Adults and children 12 years of age and over: apply topically to the area 3 to 4 times daily.

Children under 12 years of age: do not use, ask a doctor

Inactive Ingredients: Cetyl Alcohol, Citric Acid, Diazolidinyl Urea, Edetate Disodium, Glycerin, Glyceryl Monostearate, Methylparaben, Mineral Oil, Polyethylene Glycol, Propylene Glycol, Propylparaben, Purified Water, Stearic Acid, Trolamine

Hydrocort.jpg



HYDROCORTISONE

hydrocortisone acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50332-0042
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0042-1	10 in 1 BOX, UNIT-DOSE		
1		0.9 g in 1 PACKET		
2	NDC:50332-0042-2	25 in 1 BOX, UNIT-DOSE		
2		0.9 g in 1 PACKET		
3	NDC:50332-0042-4	144 in 1 BOX, UNIT-DOSE		
3		0.9 g in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/30/1990	

Labeler - HART Health (069560969)

Revised: 11/2012 HART Health