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

Dwadwat	Information
Proniict	Intormation

Product TypeHUMAN OTC DRUG LABELItem Code (Source)NDC:50332-0042

Route of Administration TOPICAL DEA Schedule

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthHYDROCORTISONE ACETATE (HYDROCORTISONE)HYDROCORTISONE10 mg in 1 g

Inactive Ingredients

muctive ingredients				
Ingredient Name	Strength			
CETYL ALCOHOL				
CITRIC ACID ACETATE				
DIAZOLIDINYL UREA				
EDETATE DISO DIUM				

GLYCERIN	
GLYCERYL MONOSTEARATE	
METHYLPARABEN	
MINERAL O IL	
PROPYLENE GLYCOL	
PROPYLPARABEN	
WATER	
STEARIC ACID	
TROLAMINE	

P	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