PROCURE- hydrocortisone acetate ointment TWIN MED, LLC

Drug Facts

Active Ingredient (per gram)

Hydrocortisone Acetate, USP (1% w/w)

Purpose

Antipruritic (Anti-Itch)

Uses

For temporary relief of minor skin irritations, itching and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, and for external gential, feminine and anal itching. Other uses of this product should be only under the advice and supervision of a doctor.

Warnings

FOR EXTERNAL USE ONLY.

Do not use

- In the eyes
- for diaper rash
- if you have vaginal discharge
- more than recommended dosage.

Ask a doctor before use if

you are pregnant or breast feeding

Stop use and ask a doctor if

 the condition worsens, or if symptoms persists for more than 7 days or 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.

Directions

- Adults and children over 2 years of age
- Apply evenly to affected area no more than 3 to 4 times daily

- Children under 2 years of age
- Do not use, consult a doctor
- Adults- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- Gently dry, patting or blotting with bathroom tissue or soft cloth before applying
- apply externally to the area up to 6 times daily or after bowel movment
- After application, discard pad. Do not flush in toilet.

Other Information

- Store at 20 °-25 °C(68 °-77 ° F)
- Avoid excessive heat and humidity.

Inactive Ingredients

Cetomacrogol 1000, Cetostearyl Alcohol, Chloracresol, Edetate Disodium, Liquid Paraffin, Propylene Glycol, Purified Water, Sodium Metabisulphite, White Soft Paraffin.

Principal Display Panel



PROCURE hydrocortisone acetate ointment Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55681-224 Route of Administration TOPICAL

Active Ingredient/Active Moiety						
Ingredient Name	Basis of Strength	Strength				
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII: W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g				

Inactive Ingredients				
Ingredient Name	Strength			
CETETH-20 (UNII: 1835H2IHHX)				
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
EDETATE SODIUM (UNII: MP1J8420LU)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM METABISULFITE (UNII: 4VON5FNS3C)				
CHLOROCRESOL (UNII: 36W53O7109)				

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:55681-224- 02	144 in 1 BOX	02/05/2013			
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product				
2	NDC:55681-224- 03	28.3 g in 1 TUBE; Type 0: Not a Combination Product	08/18/2022			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M017	02/05/2013			

Labeler - TWIN MED, LLC (009579330)

Revised: 1/2024 TWIN MED, LLC