

MEDI-FIRST- hydrocortisone acetate cream
Orazen Inc

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.

MEDI-FIRST
Hydrocortisone Cream 1%

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- for the temporary relief of itching associated with minor skin irritation, inflammation and rashed due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, sebortheic dermatitis, psoriasis and scrapes
- other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- for treatment of diaper rash
- in eyes
- for feminine itching

Stop use and ask a doctor if

- condition worsens or lasts more than 7 days, or clears up and occurs again within a few days
- you begin use of any other hydrocortisone product
- bleeding occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **for adults and children 2 years of age and older:** apply to affected area 3 to 4 times daily
- **children under 12 years of age:** for external anal itching, consult a doctor
- **children under 2 years of age:** do not use, consult a doctor
- **adults for external anal itching when practical,** cleanse the affected area with mild soap and warm water and rinse thoroughly or by patting or blotting with an appropriate cleansing pad

(continued on side panel)

- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product

Other information

- store at room temperature (do not freeze)
- tamper evident, do not use any opened or torn packets

Inactive ingredients

cetearyl alcohol, cetareth-20, ethylhexylglycerin, glycerin, glycerol fatty acid ester, mineral oil, petrolatum, phenoxyethanol, water

Questions or comments?

1-800-634-7680

Package Labeling:

1% HYDROCORTISONE CREAM

1/32oz.

ANTI-ITCH CREAM

(0.9g)

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses For temporary relief of itching associated with minor skin irritations, inflammation, or rashes. Other uses of product should be only under the advice and supervision of a doctor.

Mfg. for Medique Products
Fort Myers, FL 33967 USA

Store at Room Temperature (do not freeze)
Tamper Evident Sealed Packet

Warnings For external use only

Do not use ■ for treatment of diaper rash ■ in eyes ■ for feminine itching

Stop use and ask a doctor if ■ condition worsens or lasts more than 7 days, or clears up and occurs again within a few days ■ you begin use of any other hydrocortisone product ■ bleeding occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ apply to affected area not more than 3 to 4 times daily
■ children under 2: ask a doctor

Inactive ingredients cetearyl alcohol, cetareth-20, ethylhexylglycerin, glycerin, glycerol fatty acid ester, mineral oil, petrolatum, phenoxyethanol, water

Retain Carton for Complete Product Information



MEDI-FIRST

hydrocortisone acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71927-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-018-02	25 in 1 BOX	02/17/2023	
1	NDC:71927-018-01	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	02/17/2023	

Labeler - Orazen Inc (080916640)

Revised: 2/2023

Orazen Inc