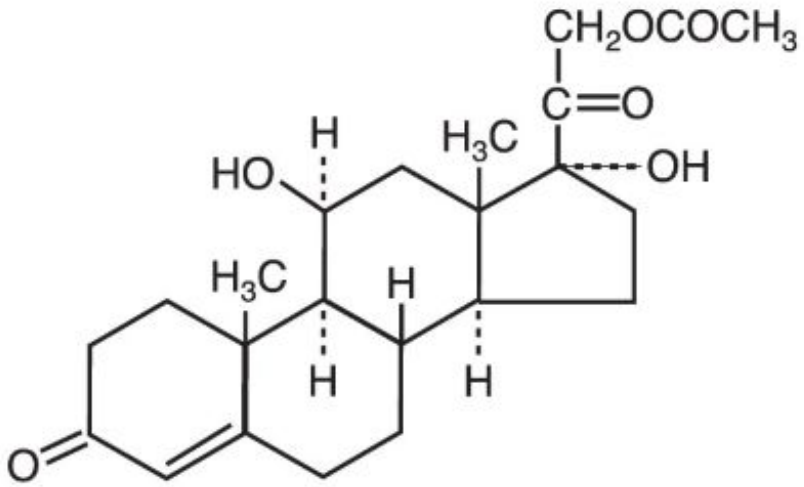
MICORT HC CREAM- hydrocortisone acetate cream cream
Legacy Pharma USA Inc.

MICORT-HC 2.5%
(Hydrocortisone acetate Cream USP)

DESCRIPTION

MiCort™ HC Cream is a topical preparation containing hydrocortisone acetate 2.5% w/w in a water washable
cream base containing cetostearyl alcohol, ceteth 20, light mineral oil, petrolatum, propylparaben, butylparaben,
citric acid, sodium citrate, and purified water. Topical corticosteroids are anti-inflammatory and anti-pruritic agents.

The structural formula, the chemical name, molecular formula and molecular weight for the active ingredient is presented below:



hydrocortisone acetate
Pregn-4-ene-3,20-dione, 21-(acetyloxy)-11, 17-dihydroxy-, (11-beta)-
$C_{23}H_{32}O_6$; mol. wt: 404.50

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, anti-pruritic, and vasoconstrictive actions. The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressing substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressing may be a valuable therapeutic adjunct for the treatment of resistant dermatoses. (See DOSAGE AND ADMINISTRATION)

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS

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General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionally larger amounts of topical corticosteroid and thus be more susceptible to systemic toxicity. (See PRECAUTIONS - Pediatric Use)

If irritation develops, topical corticosteroids should be discontinued and appropriate

therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the Infection has been adequately controlled.

Information for Patients

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.

2. Patients should be advised not to used this medication for any disorder other than for which it was prescribed.

3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.

4. Patients should report any signs of local adverse reactions especially under occlusive dressing.

5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garment may constitute occlusive dressings.

Laboratory Tests

The following tests may be helpful in evaluating the HPA axis suppression:

Urinary free cortisol test

ACTH stimulation test

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results

Pregnancy

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Teratogenic Effects

Pregnancy Category C: Corticosteroids are generally teratogenic in laboratory animals when administered systemically are relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic cffects from topically applied corticosteroids.

Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged period of time.

Nursing Mothers

It is not know whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing 's syndrome than mature patients because of a larger skin surface to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids in children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressing. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions hypopigmentation, period dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See PRECAUTIONS)

DOSAGE AND ADMINISTRATION

Topical corticosteroids are generally applied to the affected areas as a thin film two to four times daily depending on the severity of the condition.

Occlusive dressing may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the used of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED

MiCort ^{TM} HC Cream 2.5% 1 oz (28.4 g) tube NDC 83107-026-01

30 X 4 g tubes NDC 83107-026-30

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

Protect from freezing.

Keep out of reach of children. Keep tube closed when not in use.

Rev 2/2025

Manufactured for:
Legacy Pharma Inc.
George Town, Grand Cayman KY1-9012

Toll Free 1-800-727-7151

Protected under U.S. Patent No. 5,635,497.

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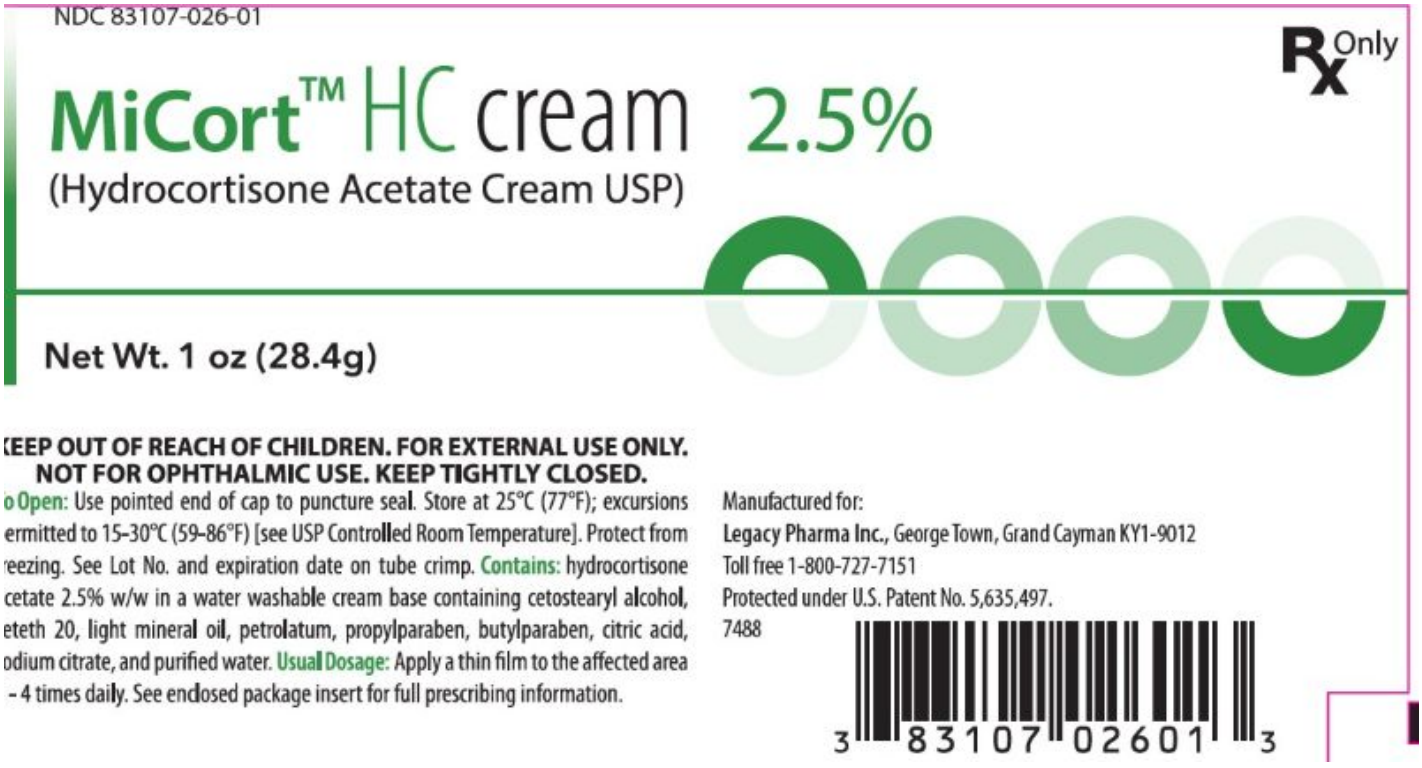

MICORT HC CREAM

hydrocortisone acetate cream cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83107-026
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

HYDROCORTISONE ACETATE (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CITRIC ACID (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83107-026-01	28.4 g in 1 CARTON; Type 0: Not a Combination Product	07/21/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040396	07/21/2025	

Labeler - Legacy Pharma USA Inc. (118831776)

Revised: 7/2025 Legacy Pharma USA Inc.