HYDROCORTISONE- hydrocortisone cream
Crown Laboratories

Hydrocortisone Cream USP, 1%, 2.5%

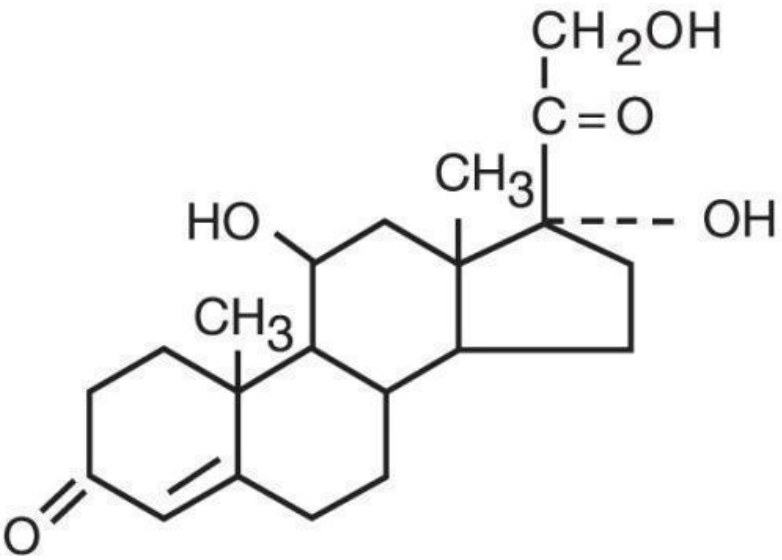
For external use only

Not for ophthalmic use

Rx Only

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Hydrocortisone is a member of this class. Chemically hydrocortisone is pregn-4-ene-3, 20-dione, 11, 17, 21-trihydroxy-, (11β)-. Its molecular formula is $C_{21}H_{30}O_5$ and molecular weight is 362.47. Its structural formula is:



$C_{21}H_{30}O_5$

362.47

Each gram of Hydrocortisone Cream USP, 1% contains 10 mg hydrocortisone USP in a cream base consisting of purified water, cetyl alcohol, glycerin, stearyl alcohol, propylene glycol, sodium lauryl sulfate, cetyl palmitate and sorbic acid.

Each gram of Hydrocortisone Cream USP, 2.5% contains 25 mg hydrocortisone USP in a cream base consisting of purified water, cetyl alcohol, glycerin, stearyl alcohol, propylene glycol, sodium lauryl sulfate, cetyl palmitate and sorbic acid.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic 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 dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for 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

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

CONTRAINDICATIONS

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

Precautions

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.

Pediatric patients may absorb proportionally larger amounts of topical corticosteroids 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 the Patient

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 use 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 garments may constitute occlusive dressings.

Latoratory Tests

The following tests may be helpful in evaluating the HPA axis suppression: Urinary free cortisol test; ACTH stimulation test

Carcinogenesis, Mutagenesis, and 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: Teratogenic effects - Pregnancy Category C

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at 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 effects 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 periods of time.

Nursing Mothers

It is not known 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 area to body weight ratio.

Hypothalamic-pituitary-adrenaI (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients 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 to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

ADVERSE REACTIONS

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

To report SUSPECTED ADVERSE REACTIONS, contact Crown Laboratories, Inc. at 1-423-926-4413 or FDA at 1-800-FDA-1088 or https://www.fda.gov/Safety/MedWatch/

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

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

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

PACKAGING AND STORAGE

Store at 20 º - 25 ºC (68 º - 77 ºF) [see USP Controlled Room Temperature].

HOW SUPPLIED

Hydrocortisone Cream USP, 1% is supplied in:

1 ounce (28.4 grams) tube NDC 0316-0186-01

454 grams jar NDC 0316-0186-16

Hydrocortisone Cream USP, 2.5% is supplied in:

20 grams tube NDC 0316-0193-20

30 grams tube NDC 0316-0193-30

454 grams jar NDC 0316-0193-16

Manufactured and Distributed by: Crown Laboratories, Inc., Johnson City, Tennessee 37604

PRINTED IN USA

Revised Dec 2017

P6306.03

Hydrocortisone Cream USP, 1% - 1oz Label

NDC 0316-0186-01

Rx Only

Hydrocortisone Cream USP, 1%

Warning: Keep out of reach of children.

For external use only.

Not for ophthalmic use.

1oz (28.4 grams)

Each gram contains: 10 mg Hydrocortisone USP in a cream base consisting of purified water, cetyl alcohol, glycerin, stearyl alcohol, propylene glycol, sodium lauryl sulfate, cetyl palmitate and sorbic acid.

Usual Dosage: 2 to 4 applications daily. See package insert for full prescribing information.

TO OPEN: Use cap to pucture seal. IMPORTANT: Do not use if seal has been puctured or is not visible.

Store at 20 º-25 ºC (68 º-77 ºF)[see USP Controlled Room Temperature].

See crimp of tube for Lot Number and Expiration Date.

Manufactured and Distributed by:

Crown Laboratories, Inc.,

Johnson City, TN 37604

P6300.01

NDC 0316-0186-01

Rx Only

Hydrocortisone Cream USP, 1%

1 oz (28.4 grams)

WARNING: Keep out of reach of children.

For external use only. Not for ophthalmic use.

Each gram contains: 10 mg Hydrocortisone USP in a cream base consisting of purified water, cetyl alcohol, glycerin, stearyl alcohol, propylene glycol, sodium lauryl sulfate, cetyl palmitate and sorbic acid.

Usual Dosage: 2 to 4 applications daily. See package insert for full prescribing information.

TO OPEN: Use cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

Store at 20°–25°C (68°–77°F) [see USP Controlled Room Temperature].

See crimp of tube for Lot Number and Expiration Date.

Manufactured and Distributed by:

Crown Laboratories, Inc.,
Johnson City, TN 37604

P6300.01

3 03160 18601 1

Hydrocortisone Cream USP, 1% -1oz Carton

NDC 0316-0186-01

Rx Only

Hydrocortisone Cream USP, 1%

Warning: Keep out of reach of children.

For external use only.

Not for ophthalmic use.

1oz (28.4 grams)

Each gram contains: 10 mg Hydrocortisone USP in a cream base consisting of purified water, cetyl alcohol, glycerin, stearyl alcohol, propylene glycol, sodium lauryl sulfate, cetyl palmitate and sorbic

acid.

Directions for puncturing tube seal: Remove cap. Turn cap upside down and place puncture tip onto tube seal. Push cap down until seal is punctured. Screw cap back on to reseal tube.

Store at 20 º-25 ºC (68 º-77 ºF)[see USP Controlled Room Temperature].

Usual Dosage: 2 to 4 applications daily. See package insert for full prescribing information.

See end of carton for Lot Number and Expiration Date.

Manufactured and Distributed by:

Crown Laboratories, Inc., Johnson City, TN 37604

P6304.02

Hydrocortisone Cream USP, 2.5% 30 grams Label

NDC 0316-0193-30

Rx Only

Hydrocortisone Cream USP, 2.5%

30 grams

WARNING: Keep out of reach of children.

For external use only. Not for ophthalmic use.

Each gram contains: 25 mg Hydrocortisone USP in a cream base consisting of purified water, cetyl alcohol, glycerin, stearyl alcohol, propylene glycol, sodium lauryl sulfate, cetyl palmitate and sorbic acid.

Usual Dosage: 2 to 4 applications daily. See package insert for full prescribing information.

TO OPEN: Use cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

Store at 20°C-25°C (68°-77°F) [see USP Controlled Room Temperature].

See crimp of tube for Lot Number and Expiration Date.

Manufactured and Distributed by:

Crown Laboratories, Inc.,

Johnson City, TN 37604

P11337.00

Hydrocortisone Cream USP, 2.5% 30 grams Carton

NDC 0316-0193-30

Rx Only

Hydrocortisone Cream USP, 2.5%

WARNING: Keep out of reach of children.

For external use only.

Not for ophthalmic use.

30 grams

Each gram contains: 25 mg Hydrocortisone USP in a cream base consisting of purified water, cetyl

alcohol, glycerin, stearyl alcohol, propylene glycol, sodium lauryl sulfate, cetyl palmitate and sorbic acid.

Usual Dosage: 2 to 4 applications daily. See package insert for full prescribing information.

Directions for puncturing tube seal: Remove cap. Turn cap upside down and place puncture tip onto tube seal. Push cap down until seal is punctured. Screw cap back on to reseal tube.

IMPORTANT: Do not use if seal has been punctured or is not visible.

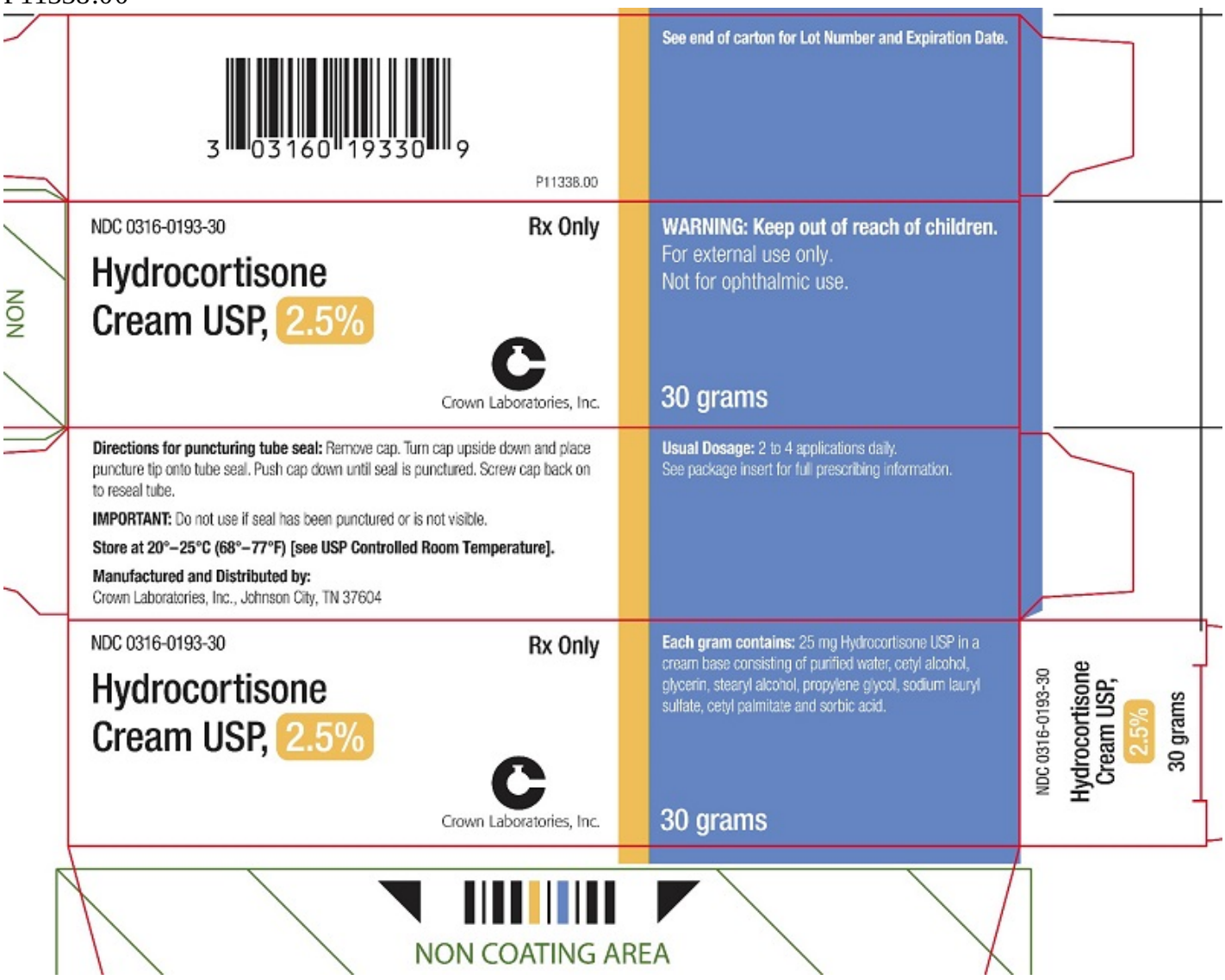
Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

See end of carton for Lot Number and Expiration Date.

Manufactured and Distributed by:

Crown Laboratories, Inc., Johnson City, TN 37604

P11338.00



HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0316-0186

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-0186-01	1 in 1 CARTON	03/09/1973	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0316-0186-16	1 in 1 CARTON	01/02/2017	
2		454 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080706	03/09/1973	

HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0316-0193
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	25 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0316-0193-30	1 in 1 CARTON	01/06/2016	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0316-0193-20	1 in 1 CARTON	01/06/2016	
2		20 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0316-0193-16	1 in 1 CARTON	01/06/2016	
3		454 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA080706	01/06/2016	

Labeler - Crown Laboratories (079035945)

Registrant - Crown Laboratories (079035945)

Establishment

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-0186, 0316-0193)

Revised: 9/2019 Crown Laboratories