HYDROCORT- hydrocortisone lotion kit
Scite Pharma

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Hydrocort Loction 2%

Hydrocortisone Lotion, USP, 2%

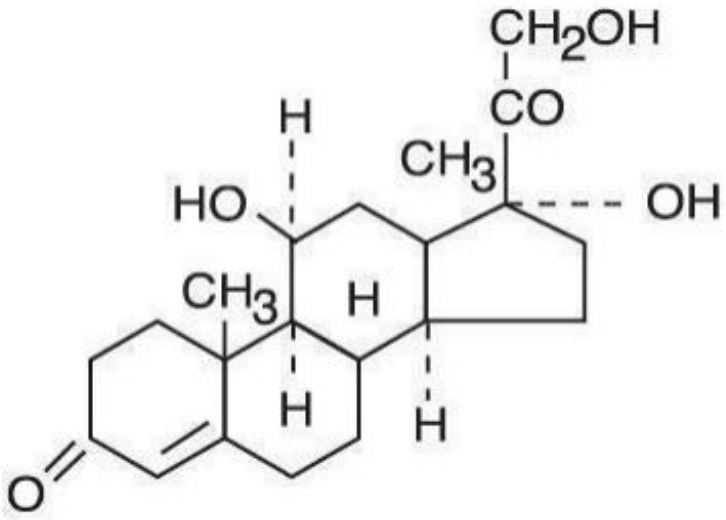
Rx Only

For external use only

Not for opthalmic use

DESCRIPTION

Topical corticosteroids constitute a class of primarily synthetic steroids used a 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, (11B)-. Its structural formula is:



$C_{21}H_{30}O_5$

362.47

Each mL of ALA-SCALP (Hydrocortisone Lotion USP), 2% contains 20 mg of hydrocortisone USP in a vehicle of isopropyl alcohol, polysorbate 20, purified water, propylene glycol, and benzalkonium chloride.

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 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 primaily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their matabolites are also excreted into the bile.

INDICATIONS AND USAGE

Hydrocortisone Lotion is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Hydrocortisone Lotion is 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, manifestation of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment system 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 develps, 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 the garments may constitute occlusive dressings.

Laboratory Tests

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

Urinary free corticol test

ACTH stimulation test

Carcinogensis, 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 mutagencity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage lavels. 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 prenant 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-adrenal (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients 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 bilaterial 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 aproximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermitis, allergic contact dermatis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

To report SUSPECTED ADVERSE REACTIONS, contact Scite Pharma, LLC at 1-866-633-9033 or FDA at 1-800-FDA-1088 or https://fda.gov/Safety/MedWatch/

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 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.

HOW SUPPLIED

Hydrocort Lotion Kit containing two 1oz (29.6 mL) bottles of hydrocortisone lotion UPS 2% and one 8oz (236.6 mL) bottle of shampoo and body wash (total kit volume: 296.8mL): NDC 79043-410-90

STORAGE

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

Manufactured for:

Scite Pharma, LLC

Canton, MS 39046

Printed in USA

REVISED: 5/2023

Shampoo & Body Wash

Shampoo & Body Wash Directions

Massage moderate amount into wet scalp and leave on scalp 2 to 3 minutes or apply to

all areas of the body and lather then rinse thoroughly.

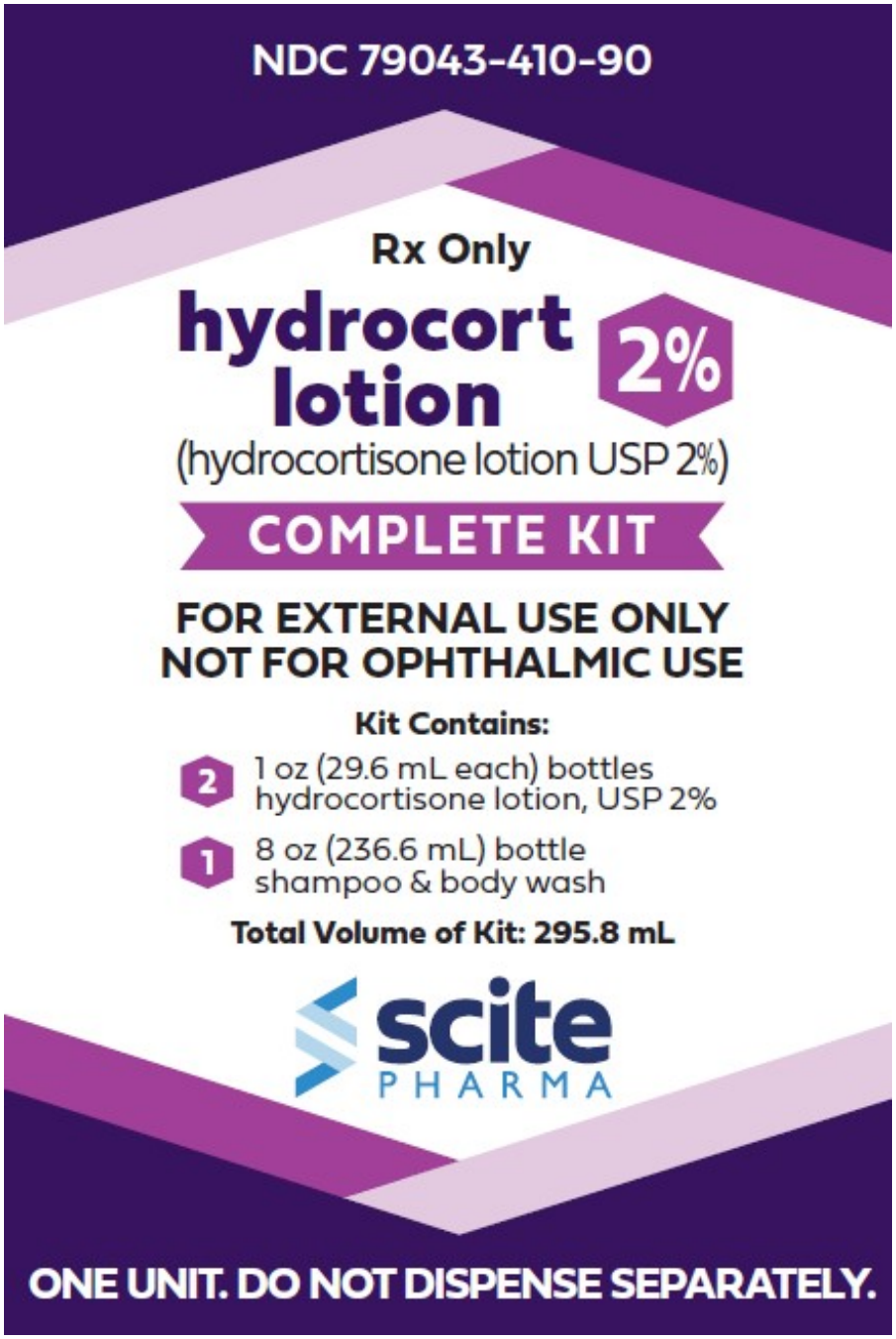
Sunburn Alert and Warnings

Suburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use sunscreen and limit sun exposure while using the product and for a week afterwards.

Warnings: For external use only, avoid contact with the eyes. If irritation occurs, wash product off, discontinue use and consult a physician.

Inactive ingredients

Inactive ingredients: Ammonium Laureth Sulfate, Purified Water, Glycolic Acid, Glycerin, Disodium Cocoamphodiacetate, Propylene Glycol, Sodium Citrate, Menthol, Fragrance, Mehylparaben, Propylparaben, Diazolidinyl Urea.



hydrocort lotion 2%

(hydrocortisone lotion USP 2%)

Each mL contains 20 mg Hydrocortisone USP in a vehicle of isopropyl alcohol, polysorbate 20, purified water, propylene glycol and benzalkonium chloride.

Usual Dosage: Apply a thin film to the affected areas 2 to 4 times daily. Store at room temperature 20°–25°C (68°–77°F) [see USP Controlled Room Temperature]. Refer to package insert for full prescribing information.

WARNING: Keep out of reach of children.

shampoo & body wash

shampoo & body wash helps gently exfoliate and cleanse the body and scalp with AHA glycolic acid. This unique formulation helps speed up the body's natural exfoliation process while also providing a cool fresh feel after a shower or bath.

Directions: Massage moderate amount into wet scalp and leave on scalp 2 to 3 minutes or apply to all areas of the body and lather then rinse thoroughly.

Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use sunscreen and limit sun exposure while using the product and for a week afterwards.

Warnings: For external use only, avoid contact with the eyes. If irritation occurs, wash product off, discontinue use and consult a physician.

Ingredients: Ammonium Laureth Sulfate, Purified Water, Glycolic Acid, Glycerin, Disodium Cocoamphodiacetate, Propylene Glycol, Sodium Citrate, Menthol, Fragrance, Methylparaben, Propylparaben, Diazolidinyl Urea.

Manufactured for: Scite Pharma, LLC
Canton, MS 39046 • 1-866-633-9033
Rev. 05/2023

N 3 79043-410-90 0

HYDROCORT

hydrocortisone lotion kit kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:79043-410

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79043-410-90	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	06/10/2023	10/01/2023

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	0 BOTTLE	1 mL in 2
Part 2	0 BOTTLE	2 mL in 2

Part 1 of 2

HYDROCORTISONE

hydrocortisone lotion lotion

Product Information	
Item Code (Source)	NDC:28595-225
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:28595-225-31	29.6 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA083231	06/10/2023	

Part 2 of 2

SHAMPOO AND BODY WASH

shampoos (non-coloring), rinse-off [hair preparations (non-coloring)] shampoo

Product Information

Route of Administration	TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**WATER** (UNII: 059QF0KO0R)	
INGR	**GLYCOLIC ACID** (UNII: 0WT12SX38S)	
INGR	**GLYCERIN** (UNII: PDC6A3C0OX)	
INGR	**PROPYLENE GLYCOL** (UNII: 6DC9Q167V3)	
INGR	**SODIUM CITRATE** (UNII: 1Q73Q2JULR)	
INGR	**FRAGRANCE 13576** (UNII: 5EM498GW35)	
INGR	**PROPYLPARABEN** (UNII: Z8IX2SC1OH)	
INGR	**AMMONIUM LAURYL SULFATE** (UNII: Q7AO2R1M0B)	
INGR	**METHYLPARABEN** (UNII: A2I8C7HI9T)	
INGR	**DIAZOLIDINYL UREA** (UNII: H5RIZ3MPW4)	
INGR	**MENTHOL, (+)-** (UNII: C6B1OE8P3W)	
INGR	**DISODIUM COCOAMPHODIACETATE** (UNII: 18L9G3U51M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		236.6 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		06/10/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/10/2023	

Labeler - Scite Pharma (117555106)