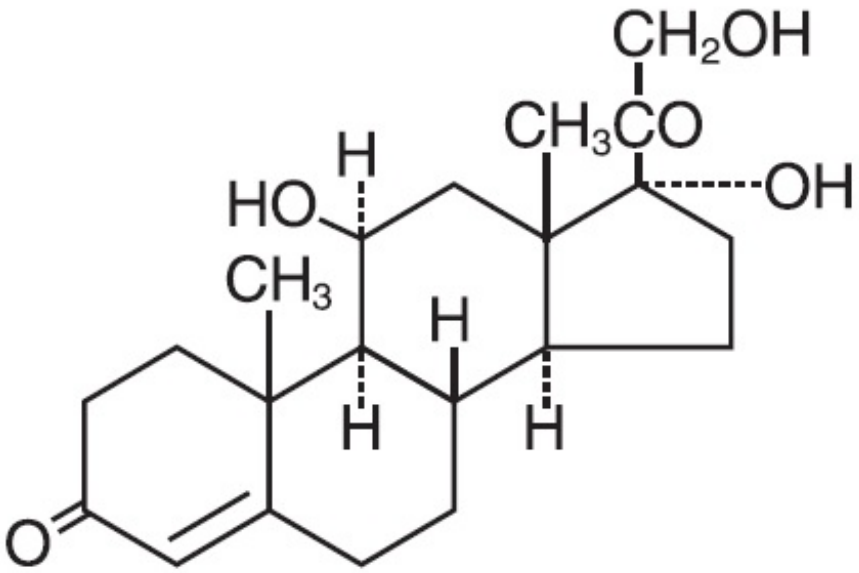
ANUSOL HC- hydrocortisone cream
Salix Pharmaceuticals, Inc

Anusol-HC® 2.5%
(hydrocortisone cream, USP)

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Anusol-HC® 2.5% (hydrocortisone cream, USP) is a topical corticosteroid with hydrocortisone 2.5% (active ingredient) in a water-washable cream containing the following inactive ingredients: benzyl alcohol, petrolatum, stearyl alcohol, propylene glycol, isopropyl myristate, polyoxyl 40 stearate, carbomer homopolymer, sodium lauryl sulfate, edetate disodium, sodium hydroxide to adjust the pH, and purified water.

Hydrocortisone has the chemical name Pregn-4-ene-3,20-dione, 11,17, 21, trihydroxy-,(11β) - and the following chemical structure:



MOLECULAR FORMULA	MOLECULAR WEIGHT	CAS REGISTRY NUMBER
$C_{21}H_{30}O_5$	362.47	50-23-7

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

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

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.

If HPA axis suppression is noted (by using the urinary free cortisol and ACTH stimulation tests) an attempt should be made to withdraw the drug or to reduce the frequency of application.

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 that for which it has been 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.

Laboratory Tests:

The urinary free cortisol test and the ACTH stimulation test may be helpful in evaluating the HPA axis suppression.

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 hydrocortisone have revealed negative results.

Pregnancy:

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-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 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	Acneiform eruptions	Skin atrophy
Itching	Hypopigmentation	Striae
Irritation	Perioral dermatitis	Miliaria
Dryness	Allergic contact dermatitis	
Folliculitis	Maceration of the skin	
Hypertrichosis	Secondary infection	

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Anusol-HC® 2.5% (hydrocortisone cream, USP) should be applied to the affected area 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

Anusol-HC 2.5% (hydrocortisone cream, USP) is supplied as follows:
NDC 65649-401-30 30 g tube

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. PROTECT FROM FREEZING.

Distributed by:
Salix Pharmaceuticals, a division
of Bausch Health US, LLC
Bridgewater, NJ 08807 USA

Manufactured by:
Padagis® US LLC
Minneapolis, MN 55427 USA

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Rev. 06/2023
9521003
2204609 7C800 9L PH4

PACKAGE LABEL PRINCIPAL DISPLAY PANEL –Carton 30 Grams

NDC 65649-401-30

Rx only

Anusol-HC® 2.5%

(hydrocortisone cream, USP)

For External Use Only
For Topical Use Only

Net Wt. 30 g

Salix
PHARMACEUTICALS

ANUSOL HC

hydrocortisone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65649-401

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65649-401-30	1 in 1 CARTON	06/06/1984	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088250	06/06/1984	

Labeler - Salix Pharmaceuticals, Inc (793108036)

Establishment

Name	Address	ID/FEI	Business Operations
Padagis US LLC		967694121	MANUFACTURE(65649-401)

Revised: 6/2023 Salix Pharmaceuticals, Inc