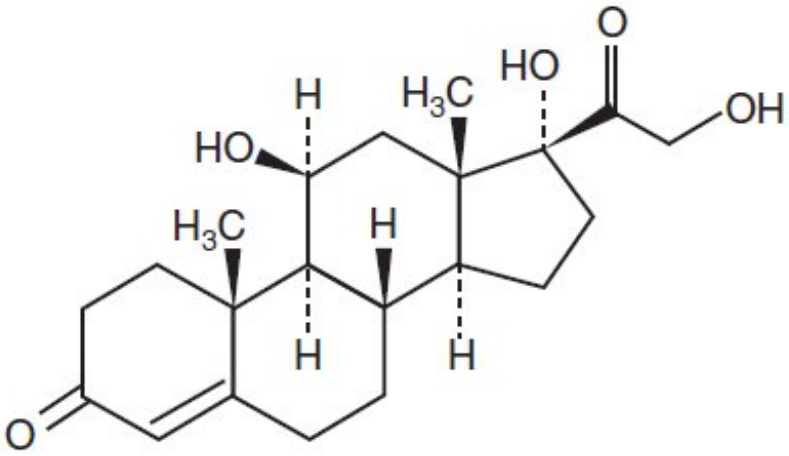
HYDROCORTISONE- hydrocortisone lotion
Padagis Israel Pharmaceuticals Ltd

Hydrocortisone Lotion USP, 2.5%

Rx Only

DESCRIPTION

Each mL of Hydrocortisone Lotion USP, 2.5% contains 25 mg of hydrocortisone, USP in a vehicle consisting of carbomer homopolymer type C, ceteareth-20, cetyl alcohol, dehydroacetic acid, DMDM hydantoin, fragrance, glyceryl stearate, isopropyl palmitate, lactic acid, light mineral oil, myristyl alcohol, myristyl lactate, PEG-100 stearate, purified water, sodium hydroxide, sodium PCA, and stearyl alcohol. Chemically, hydrocortisone is [Pregn-4-ene-3, 20-dione, 11, 17, 21-trihydroxy-, (11ß)-] with the molecular formula $C_{21}H_{30}O_5$ and is represented by the following structural formula:



Its molecular weight is 362.46 and its CAS Registry Number is 50-23-7. The topical corticosteroids, including hydrocortisone, constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

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.

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 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 dressings.

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 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: 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-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, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral 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

Shake well before using. 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

Hydrocortisone Lotion USP, 2.5% is available as follows:

2 fl oz (59 mL) bottle (NDC 45802-**937**-16)

4 fl oz (118 mL) bottle (NDC 45802-**937**-26)

Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature]. Keep tightly closed. Keep out of the reach of children.

Manufactured by Padagis
Yeruham, Israel

www.padagis.com

Rev 03-23

Package/Label Display Panel

NDC 45802-937-16

Rx Only

Hydrocortisone Lotion USP, 2.5%

For Topical Use Only

27C16 RC F2

2 FL OZ (59 mL)

PEEL HERE

The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.

S/N [insert product's serial number]
Lot [insert product's lot number]
Exp [insert product's expiration date]

HYDROCORTISONE

hydrocortisone lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:45802-937
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
MYRISTYL LACTATE (UNII: 1D822OC34X)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:45802-937-16	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2008	
2	NDC:45802-937-	118 mL in 1 BOTTLE; Type 0: Not a Combination	05/23/2008	

2	26	Product	05/23/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089074	05/23/2008	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 3/2023

Padagis Israel Pharmaceuticals Ltd