HYDROCORTISONE- hydrocortisone lotion
Perrigo New York Inc
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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 Perrigo
Bronx, NY 10457
Distributed By
Perrigo®
Allegan, MI 49010 • www.perrigo.com
Rev 04-17
: 3X116 RC F7

Package/Label Display Panel
PEEL HERE
Rx Only
Hydrocortisone Lotion USP, 2.5%
For Topical Use Only
4 FL OZ (118 mL)
Hydrocortisone Lotion USP, 2.5%

For Topical Use Only

2 FL OZ (59 mL)
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 carboxymethylcellulose sodium, isopropyl alcohol, purified water, and proportioned amounts of the following inactive ingredients: aluminum, colorants, isopropyl myristate, sodium hydroxide, sodium PCA, and stearyl alcohol. Hydrocortisone is a 21-alkylated progesterone with the chemical formula C_{21}H_{28}O_5. It is a white, odorless, crystalline powder with a mol. wt. of 382.46 and a CAS Registry Number of 50-23-7. Hydrocortisone is one of the topically applied corticosteroids, being one of the few corticosteroids that are used in the treatment of a wide variety of inflammatory conditions.

CLINICAL PHARMACOLOGY
Topical corticosteroids are non-systemic anti-inflammatory agents. They are applied directly to the skin and penetrate the epidermis and dermis. The mechanism of anti-inflammatory action is thought to be related to the inhibition of phospholipase A2, which is involved in the production of pro-inflammatory cytokines.

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

PRECAUTIONS
General - Systemic absorption of topical corticosteroids may produce adverse hypothalamic-pituitary-adrenal (HPA) axis suppression manifested by suppression 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 generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of acute adrenal insufficiency may develop upon abrupt discontinuation of systemic corticosteroid therapy. Therefore, patients being treated with systemic corticosteroids should be instructed appropriately to taper the dosage before discontinuation. If discontinuation of therapy becomes necessary, treatment of adrenal insufficiency and potassium depletion should be initiated before discontinuation of the corticosteroid.

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

DOSE 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 pruritic or eczematous 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 Perrigo
 Bronx, NY 10457
Distributed By
Perrigo®
Arlington, N.H. 03849 • www.perrigo.com
Rev 04-17

Hydrocortisone Lotion USP, 2.5%
For Topical Use Only
2 FL OZ (59 mL)
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

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#### Active Ingredient/Active Moiety

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#### 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:45802-937-26 | 118 mL in 1 BOTTLE; Type 0: Not a Combination 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** - Perrigo New York Inc (078846912)

Revised: 11/2018

Perrigo New York Inc