Triamcinolone Acetonide Ointment USP, 0.1% 

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as 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

Triamcinolone Acetonide Ointment is 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 preparations.

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. Topically applied corticosteroids can be absorbed in sufficient amounts to produce manifestations of HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children 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 children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (reactions are listed in approximate decreasing order of occurrence): burning, itching, irritation, dryness, and/or other dermatologic reactions. The most common local reactions occur at the site of dermal penetration and include skin atrophy, pruritus, striae, and milia. To report SUSPECTED ADVERSE REACTIONS, contact Teligent Pharma, Inc. at 1-866-697-1441, 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, General).

DOSAGE AND ADMINISTRATION

Apply a thin film to the affected area two to three times daily.

Dressage Technique

Occlusive dressings may be used for the management of psoriatic or other recalcitrant conditions. A thin film of ointment to the lesion, cover with a pliable nonporous film, and seal the edges. If needed, additional moisture may be provided by covering the lesion with a dampened clean cotton cloth before the nonporous film is applied or by briefly wetting the affected area with water immediately prior to applying the medication.

The frequency of changing dressings is best determined on an individual basis. It may be convenient to apply Triamcinolone Acetonide Ointment under an occlusive dressing in the evening and to remove the dressing the morning (i.e., 12-hour occlusion). When utilizing the 12-hour occlusion regimen, additional ointment should be applied, without occlusion, during the day. Reapplication is essential at each dressing change.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED

Triamcinolone Acetonide Ointment USP, 0.1% is supplied in the following sizes:

15 g tube – NDC 52565-014-15
80 g tube – NDC 52565-014-80
1% (545 g) jar – NDC 52565-014-26

Storage
Store at 20° - 25°C (68° - 77°F). [see USP Controlled Room Temperature]
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS, General).

DOSE AND ADMINISTRATION

Apply a thin film to the affected area two to three times daily.

Occlusive Dressing Technique

Occlusive dressings may be used for the management of psoriasis or other recalcitrant conditions. Apply a thin film of ointment to the lesion, cover with a pliable nonocclusive film, and seal the edges. If needed, additional moisture may be provided by covering the lesion with a dampened clean cotton cloth before the nonporous film is applied or by briefly wetting the affected area with water immediately prior to applying the film.

The frequency of changing dressings is best determined on an individual basis. It may be convenient to apply Triamcinolone Acetonide Ointment under an occlusive dressing in the evening and to remove the dressing in the morning (i.e., 12-hour occlusion). When utilizing the 12-hour occlusion regimen, additional ointment should be applied, without occlusion, during the day. Reapplication is essential at each dressing change.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antibiotic therapy instituted.

CONTRAINdications

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

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 more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of any topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression and for impairment of the thermal homeostasis. If HPA axis suppression is noted, it should be treated by decreasing the dose of topical steroid or by discontinuing it completely. Patients should be advised not to use this medication for any disorder other than that for which it was prescribed.

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.

These preparations are not for opthalmic use.

Pediatric Use

Pediatric patients do not require a dosage reduction when using topical corticosteroids. The potential risks of topical corticosteroids must be considered in pediatric patients receiving systemic corticosteroids. Additional risk factors for systemic corticosteroid therapy may interfere with the growth and development of children. Therefore, the use of topical corticosteroids in children should be limited to those cases where the benefit-to-risk ratio is favorable. Once given, complete withdrawal of topical corticosteroids may not be possible unless the underlying condition is first brought under control through appropriate therapy.

Liquid preparations of corticosteroids should not be used in infants because of the risk of development of adrenal suppression, which may interfere with normal growth. In children, the skin, especially the skin of the face and scalp, is more susceptible to systemic toxicity from topically applied corticosteroids than in adults. Therefore, the use of corticosteroids in children should be limited to those instances where the benefit-to-risk ratio is favorable. In children treated with systemic corticosteroids, the growth and development of children should be monitored periodically during therapy with corticosteroids. When given systemically, corticosteroids may also alter response to anesthesia. The effect of systemic corticosteroids on growth rates in children is reversible upon withdrawal of therapy.

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 corticosteroids induced HPA axis suppression and Cushing’s syndrome than mature patients because of a larger skin surface area to body weight ratio. HPA axis suppression, Cushing’s syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed skeletal maturation, and decrease in the rate of weight gain. In children treated with systemic corticosteroids, the growth and development of children should be monitored periodically during therapy with corticosteroids. When given systemically, corticosteroids may also alter response to anesthesia.

AURERECTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. Reactions may include allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact