

PRODUCT MONOGRAPH

VIADERM KC CREAM & VIADERM KC OINTMENT

(Triamcinolone Acetonide, Nystatin, Neomycin, Gramicidin)

Topical corticosteroid, anti-inflammatory antibacterial and antifungal
agents

Taro Pharmaceuticals Inc.
Downsview, Ontario

DATE OF PREPARATION:
January 7, 1987

3HN862432

NAME OF DRUG

VIADERM KC CREAM & VIADERM KC OINTMENT

THERAPEUTIC CLASSIFICATION

Topical Corticosteroid, anti-inflammatory, antibacterial and antifungal.

ACTION

VIADERM KC CREAM & VIADERM KC OINTMENT provide relief from the itching and burning associated with secondarily infected inflammatory conditions by virtue of:

- 1) the anti-inflammatory antipruritic and vasoconstrictive properties of triamcinolone acetonide,
- 2) the broad spectrum anti-bacterial activity of neomycin and gramicidin
- 3) the anti-candidal activity of nystatin.

INDICATIONS AND CLINICAL USE

VIADERM KC CREAM & VIADERM KC OINTMENT are indicated for the relief of corticosteroid-responsive dermatoses complicated or threatened by bacterial and/or candidal infections. Conditions most commonly infected include acute atopic dermatitis, exfoliative erythrodermas, neurodermatitis, nummular eczema, acute contact dermatitis, chronic eczema (except of lower leg), chronic familiar benign pemphigus and intertriginous lesions.

CONTRAINDICATIONS

VIADERM KC CREAM & VIADERM KC OINTMENT should not be used for primary skin infections. VIADERM KC CREAM & VIADERM KC OINTMENT are contraindicated in tuberculous and most viral lesions of the skin (including herpes simplex, vaccinia and varicella) and fungal skin lesions except candidiasis. VIADERM KC CREAM & VIADERM KC OINTMENT are also contraindicated in individuals with a history of hypersensitivity to their components. VIADERM KC CREAM & VIADERM KC OINTMENT should not be used for ophthalmic use nor should they be applied in the external auditory canal of patients with perforated eardrums.

WARNINGS

Adrenal suppression and other systemic effects may occur with topical steroid preparations and their possible occurrence must be kept in mind, particularly when these preparations are used over large areas or for an extended period of time. Prolonged use may lead to steroid withdrawal when the medication is discontinued.

VIADERM KC CREAM & VIADERM KC OINTMENT should not be used under occlusive dressings. The safety of topical corticosteroid preparations during pregnancy and lactation has not been established. the potential benefit of the use of topical corticosteroids during pregnancy and lactation should be weighed against the possible hazards to the fetus or the nursing infant.

PRECAUTIONS

If local irritation or sensitization develops, VIADERM KC CREAM & VIADERM KC OINTMENT should be discontinued and appropriate therapy instituted. Topical corticosteroids should be used with caution on lesions close to the eye. Patients should be advised to inform subsequent physicians of the prior use of corticosteroids. Prolonged use of corticosteroids may produce atrophy of the skin and subcutaneous tissues, particularly on flexor surfaces and on the face. If this is noted, discontinue the use of the product. Topical corticosteroids should be used with caution in patients with stasis dermatitis and other skin diseases associated with impaired circulation. Prolonged use of topical antibiotics should be avoided.

Because of the potential hazard of nephrotoxicity and ototoxicity of neomycin, prolonged use or the use of large amounts should be avoided in conditions where absorption is possible (such as burn lesions or trophic ulcerations). As with any antibiotic preparation, prolonged use may lead to overgrowth of non-susceptible and resistant organisms. Should this occur, suitable anti-microbial therapy must be instituted.

If a symptomatic response is not noted within 7 days, the patient should be re-evaluated.

Hypersensitivity reactions to topically applied sterids, nystatin or gramicidin are rare. However, current medical literature indicates an increase in the incidence of patients allergic to neomycin. VIADERM KC CREAM & VIADERM KC OINTMENT should be discontinued and appropriate therapy initiated if there are signs of allergic reactions.

ADVERSE REACTIONS

The following adverse skin reactions have been reported with the use of topical corticosteroids:

Dryness, itching, burning, local irritation, skin atrophy, striae, atrophy of subcutaneous tissue, folliculitis, acneform eruptions, hypertrichosis, miliaria, change in skin pigmentation and telangiectasia. Adrenal suppression has also been reported following topical corticosteroid therapy. Posterior subcapsular cataracts have been observed following systemic corticosteroid therapy. Hypersensitivity reactions to neomycin, gramicidin and nystatin have been reported. Systemic neomycin toxicity has occurred rarely following topical administration; tinnitus and deafness have also been reported. Overgrowth of non-susceptible organisms has occurred.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

Percutaneous absorption of corticosteroids can occur, especially if used over a large area for prolonged periods of time. If large amounts of corticosteroids are absorbed, toxic effects may include mild reversible suppression of adrenal function, ecchymoses of the skin, peptic ulceration, hypertension, aggravation of infections, hirsutism, acne, edema and muscle weakness due to protein depletion. Prolonged use of large amounts of VIADERM KC CREAM OR VIADERM KC OINTMENT would likely increase the absorption of neomycin which in turn would enhance the potential for nephrotoxicity and ototoxicity as well as ulceration.

No specific antidote is available, treatment should be primarily symptomatic and administration of the cream or ointment discontinued.

DOSAGE AND ADMINISTRATION

Each g of VIADERM KC CREAM OR VIADERM KC OINTMENT contains triamcinolone acetonide 1 mg, neomycin base (as sulfate) 2.5 mg, gramicidin 0.25 mg, nystatin 100,000 units.

Apply a small quantity two or three times daily. Do not apply more than prescribed by physician. For external use only.

DOSAGE FORMS

VIADERM KC CREAM is available in 15, 30 and 100 g collapsible tubes and in 454 g jars.

VIADERM KC OINTMENT is available in 15 g and 90 g tubes and in 400 g jars.

Store at room temperature, 15-30°C.