PRESCRIBING INFORMATION
AND
PATIENT MEDICATION INFORMATION

PrVIADERM K.C.® CREAM
PrVIADERM K.C.® OINTMENT

(Triamcinolone Acetonide 1 mg/g, Nystatin 100,000 units/g,
Neomycin base (as sulphate) 2.5 mg/g, and Gramicidin 0.25 mg/g)

Topical corticosteroid, anti-inflammatory, antibacterial and antifungal agents

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Topical	Cream/Ointment: 1 mg/g triamcinolone acetonide, 100,000 units/g nystatin, 2.5 mg/g neomycin (as sulphate), 0.25 mg/g gramicidin	**Cream:** Cetomacrogol emulsifying wax, citric acid, ethanol, methylparaben, mineral oil, perfume, propylparaben, propylene glycol, purified water, sodium phosphate dibasic, white petrolatum **Ointment:** mineral oil, white petrolatum

INDICATIONS AND CLINICAL USE

- Viaderm K.C.® Cream and Viaderm K.C.® Ointment are indicated for the relief of corticosteroid-responsive inflammatory or pruritic dermatoses caused, threatened or complicated by infection due to bacteria and/or candida.
- Viaderm K.C.® Cream is indicated for Pruritus ani and pruritus vulvae.

Conditions most commonly infected include acute atopic dermatitis, exfoliative eythrodermas, neurodermatitis, nummular eczema, acute contact dermatitis, chronic eczema (except of lower leg), chronic familiar benign pemphigus and intertriginous lesions.

Viaderm K.C.® Cream and Viaderm K.C.® Ointment contain antibiotic ingredients, gramicidin and neomycin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of gramicidin and neomycin, Viaderm K.C.® Cream and Viaderm K.C.® Ointment should only be used for the authorized indication and clinical use.

CONTRAINDICATIONS

Viaderm K.C. ® Cream and Viaderm K.C. ® Ointment are contraindicated as follow:

In Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the product monograph.

- In Tuberculous and most viral lesions of the skin (including herpes simplex, vaccinia and varicella) and fungal skin lesions except candidiasis.
- In primary skin infections.
- For ophthalmic use
- For application to the external auditory canal of patients with perforated eardrums or patients with otitis media.
- As Occlusive therapy in patients with atopic dermatitis.

WARNINGS AND PRECAUTIONS

General
Patients should be advised to inform subsequent physicians of the prior use of corticosteroids. Viaderm K.C.® Cream and Viaderm K.C.® Ointment should not be used under occlusive dressings (**see ADVERSE REACTIONS**).

Cardiovascular
Topical corticosteroids should be used with caution in patients with stasis dermatitis and other skin diseases associated with impaired circulation. If a symptomatic response is not noted within 7 days, the patient should be re-evaluated. Prolonged use of topical antibiotics should be avoided.

Endocrine and Metabolism
Although adrenal suppression and other systemic adverse effects are rare with topical corticosteroid preparations, 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.

Because of the potential hazard of nephrotoxicity and ototoxicity, avoid prolonged use or the use of large amounts in the treatment of skin infections following burns, tropic ulceration and other conditions when absorption of neomycin is possible.

Gramicidin absorption following topical administration is unlikely; however, hemolysis may occur should the drug enter the blood. If gramicidin is allowed in close proximity to the sub-arachnoid space, a chemical arachnoiditis may occur (**see ADVERSE REACTIONS**).

Ophthalmologic
Topical corticosteroids should be used with caution on lesions close to the eye. Posterior subcapsular cataracts have been observed following systemic corticosteroid therapy (**see ADVERSE REACTIONS**).

Sensitivity
Hypensitivity of nystatin is extremely uncommon. Sensitivity reactions following the topical use of gramicidin or triamcinolone acetonide are rarely encountered. Burning, itching, irritation, dryness, erythema, folliculitis, hypertrichosis, acnelform eruptions, tinnitus, deafness and hypopigmentation have been reported with topical corticosteroids.

An increase in the incidence of patients allergic to neomycin has been reported in literature.

Neomycin itself may cause an allergic otitis extema. Systemic neomycin toxicity has occurred rarely following topical administration; tinnitus and deafness have been reported (**see ADVERSE REACTIONS**).

Susceptibility/Resistance

Development of Drug Resistant Bacteria: Prescribing Viaderm K.C. ® Cream and Viaderm K.C. ® Ointment in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of resistant organisms.

Potential for Microbial Overgrowth: As with any antibiotic preparation, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi other than candida. Constant observation of the patient is essential. Should superinfection due to non-susceptible organisms occur, Viaderm K.C.® Cream and Viaderm K.C.® Ointment should be discontinued and appropriate therapy instituted.

Skin

When steroid preparations are used for long periods in intertriginous areas or under occlusive dressings, striae may occur. Damage to collagen, which constitutes a middle layer of the tympanic membrane, may occur. Delayed healing and systemic effects, including adrenal suppression and subcapsular cataracts, may occur if absorbed in appreciable amounts.

If local irritation or sensitization develops, Viaderm K.C.® Cream and Viaderm K.C.® Ointment should be discontinued and appropriate therapy instituted. 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.

The use of occlusive dressings is not recommended with products containing anti-infective agents (**see ADVERSE REACTIONS**).

Special Populations

Pregnant Women: 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 should be weighed against possible hazards to the fetus.

Nursing Women: It is not known whether Topical Corticosteroids are excreted in human milk. Topical Corticosteroids should not be used during breast feeding unless the potential benefit justifies the potential risk to the nursing infant.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

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, acneiform eruptions, hypertrichosis, 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.

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

Viaderm K.C.® Cream: Each gram contains triamcinolone acetonide 1 mg, nystatin 100,000 units, neomycin base (as sulphate) 2.5 mg, and gramicidin 0.25 mg.

Viaderm K.C.® Ointment: Each gram contains triamcinolone acetonide 1 mg, nystatin 100,000 units, neomycin base (as sulphate) 2.5 mg, and gramicidin 0.25 mg.

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

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

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 K.C.® Cream and Ointment would likely increase the absorption of neomycin which in turn would enhance the potential for nephrotoxicitiy and ototoxicity as well as ulceration.

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

ACTION AND CLINICAL PHARMACOLOGY

Viaderm K.C.® Cream and Viaderm K.C.® Ointment (Triamcinolone Acetonide, Nystatin, Neomycin Sulfate and Gramicidin) provide relief from the itching and burning associated with secondarily infected inflammatory conditions by virtue of:

- the anti-inflammatory antipruritic and vasoconstrictive properties of triamcinolone acetonide;
- the broad spectrum anti-bacterial activity of neomycin and gramicidin;
- the anti-candidal activity of nystatin.

STORAGE AND STABILITY

Store at room temperature, 15 °C – 30 °C.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Viaderm K.C.® Cream is a light yellow, smooth cream. Viaderm K.C.® Ointment is a yellow, smooth ointment.

Viaderm K.C.® Cream: Each gram contains 1 mg triamcinolone acetonide, 100,000 units nystatin, 2.5 mg neomycin (as sulphate), 0.25 mg gramicidin, cetomacrogol emulsifying wax, citric acid, ethanol, methylparaben, mineral oil, perfume, propylparaben, propylene glycol, purified water, sodium phosphate dibasic, white petrolatum.

Viaderm K.C.® Ointment: Each gram contains 1 mg triamcinolone acetonide, 100,000 units nystatin, 2.5 mg neomycin (as sulphate), 0.25 mg gramicidin, mineral oil, and white petrolatum.

Viaderm K.C.® Cream is available in 15 g, 30 g, and 60 g metal tubes, and in 454 g jars.

Viaderm K.C.® Ointment is available in 15 g and 30 g metal tubes.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

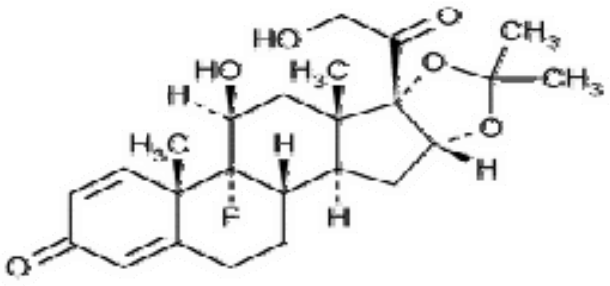
Drug Substances

Proper name: Triamcinolone Acetonide

Chemical name: Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-, (11 β,16 α)-.
9-Fluoro-11 β,16 α,17,21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone

Molecular formula and molecular mass: $C_{24}H_{31}FO_6$
434.50

Structural formula:



Physicochemical properties:

Description: White to cream-colored, crystalline powder, having not more than a slight odor.

Solubility: Sparingly soluble in dehydrated alcohol, in chloroform, and in methanol; practically insoluble in water.

Proper name: Neomycin Sulfate

Physicochemical properties:

Description: White to slightly yellow powder, or cryodesiccated solid. Is odorless or practically so and is hygroscopic. Its solutions are dextrorotatory.

Solubility: Freely soluble in water; very slightly soluble in alcohol; insoluble in acetone, in chloroform, and in ether.

Proper name: Gramicidin

Physicochemical properties:

Description: White or practically white, odorless, crystalline powder.

Solubility: Soluble in alcohol; insoluble in water.

Melting Temperatures: Not lower the 229 °C, determined after drying.

Proper name: Nystatin

Physicochemical properties:

Description: Yellow to light tan powder, having an odor suggestive of cereals. Is hygroscopic, and is affected by long exposure to light, heat, and air.

Solubility: Freely soluble in dimethylformamide and in dimethyl sulfoxide; sparingly to slightly soluble in methanol, in *n*-propyl alcohol, and in *n*-butyl alcohol; practically insoluble in water and in alcohol; insoluble in chloroform and in ether.

pH: Between 6.0 and 8.0, in a 3% aqueous suspension

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

VIADERM K.C.®
(Triamcinolone Acetonide, Nystatin, Neomycin Sulfate, and Gramicidin Cream and Ointment)

Read this carefully before you start taking **Viaderm K.C.®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Viaderm K.C.®**.

What is Viaderm K.C.® used for?
Viaderm K.C.® (Triamcinolone Acetonide, Nystatin, Neomycin Sulfate, and Gramicidin) is used to provide relief from the itching, burning, and swelling caused by bacterial and/or fungal infections.

Viaderm K.C. ® Cream and Viaderm K.C. ® Ointment contain antibacterial ingredients called gramicidin and neomycin, and should be used exactly as directed by your health care professional.

How does Viaderm K.C.® work?
Viaderm K.C.® is antibacterial and antifungal which destroy the bacteria and fungi (yeasts) causing the skin infections.

How to take Viaderm K.C.®?
Misuse or overuse of Viaderm K.C. ® Cream and Viaderm K.C. ® Ointment could lead to the growth of bacteria that will not be killed by gramicidin and/or neomycin (resistance). This means that Viaderm K.C. ® Cream and Viaderm K.C. ® Ointment or other medicines that contain gramicidin and/or neomycin may not work for you in the future.

Do not share your medicine.

What are the ingredients in Viaderm K.C.®?
Medicinal ingredients: Triamcinolone Acetonide, Nystatin, Neomycin Sulfate, and Gramicidin
Non-medicinal ingredients: For cream*:* cetomacrogol emulsifying wax, citric acid, ethanol, methylparaben, mineral oil, perfume, propylparaben, propylene glycol, purified water, sodium phosphate dibasic, white petrolatum. For ointment: mineral oil, white petrolatum

Viaderm K.C.® comes in the following dosage forms:
Viaderm K.C.® Cream (Triamcinolone Acetonide 1 mg/g, Nystatin 100,000 units/g, Neomycin base (as sulphate) 2.5 mg/g, and Gramicidin 0.25 mg/g) is available in 15 g, 30 g, and 60 g tubes, and in 454 g jars.

Viaderm K.C.® Ointment (Triamcinolone Acetonide 1 mg/g, Nystatin 100,000 units/g, Neomycin base (as sulphate) 2.5 mg/g, and Gramicidin 0.25 mg/g) is available in 15 g and 30 g tubes.

Do not use Viaderm K.C.®:

- if you are allergic to Triamcinolone Acetonide, Nystatin, Neomycin Sulfate, and Gramicidin or any of its non-medicinal ingredients (See What are the ingredients of Viaderm K.C.®),
- if you have primary skin infections,
- if you have any serious skin lesions, most viral lesions of the skin (including chicken pox (varicella) cold sores or genital herpes (Herpes simplex)), and fungal skin lesions except caused by yeasts infections,
- in your eyes,
- in the outer area of your ear if you have an ear infection or holes in your eardrums (see p. 4), and
- under covered skin dressing if you have skin swelling and infections

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Viaderm K.C.®. Talk about any health conditions or problems you may have, including:

- your previous use of corticosteroids,
- if your condition has not changed within 7days,
- if you use it for large skin areas,
- if you have skin lesions close to the eye, and
- if you have allergic reactions such as burning, itching, irritation, dryness, and skin discoloration.

Other warnings you should know about:

- Avoid contact with the eyes. If accidental contact occurs, rinse the eyes thoroughly with water
- If further skin irritation develops or the infection worsens, contact your doctor.
- Avoid continuous or prolonged use as potential adverse effects increase with longer use.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Viaderm K.C.®:
Drug interactions studies have not been done for Viaderm K.C.®

How to take Viaderm K.C.®:
Small quantity 2 or 3 times daily.

Usual dose:
Apply a small amount to the affected area 2 or 3 times daily.
Do not apply to open wounds or burns to avoid absorption of the drug(s) into the blood.
Do not apply more than prescribed by the doctor. For external use only.

Overdose:

If you think you have applied too much Viaderm K.C.®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using Viaderm K.C.®?

- Skin reactions such as burning, itching, irritation, dryness, and skin discoloration.

These are not all the possible side effects you may feel when taking Viaderm K.C.®. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature between 15ºC and 30ºC.
Keep out of reach and sight of children.

If you want more information about Viaderm K.C.®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the manufacturer's website http://www.taro.ca, or by calling 1-800-268-1975.

This leaflet was prepared by Taro Pharmaceuticals Inc.
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