

NEW ZEALAND DATA SHEET

1 Viaderm KC Cream & Ointment

Gramicidin; neomycin as sulphate; triamcinolone acetonide; nystatin

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cream: 1 gram contains the following active ingredients:

- 0.025% gramicidin
- 0.25% neomycin
- 100 000U nystatin
- 0.1% triamcinolone acetonide

Ointment: 1 gram contains the following active ingredients:

- 0.025% gramicidin
- 0.25% neomycin
- 100 000U nystatin
- 0.1% triamcinolone acetonide

For the full list of excipients, see **Section 6.1 List of excipients**.

3 PHARMACEUTICAL FORM

Topical cream and topical ointment

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The topical treatment of superficial bacterial infections, cutaneous candidosis and dermatological conditions known to respond to topical steroid therapy when threatened or complicated by bacterial or candidal superinfections.

These include:

- atopic eczema
- contact eczema
- follicular eczema
- infantile eczema
- anogenital pruritis (anal and vulval pruritis)
- nummular eczema
- post-traumatic infective eczema
- seborrhoeic or flexural eczema
- neurodermatitis
- psoriasis.

4.2 Dose and method of administration

Adults and Children:

Apply to the affected areas two to four times daily.

Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical corticosteroid preparations.

Elderly:

Natural thinning of the skin occurs in the elderly; hence corticosteroids should be used sparingly and for short periods of time.

4.3 Contraindications

In tuberculosis and most viral lesions of the skin, particularly herpes simplex, vaccinia and varicella. Also, in fungal lesions not susceptible to nystatin. In patients with hypersensitivity to any of the components.

Should not be applied to the external auditory canal in patients with perforated eardrums.

4.4 Special warnings and precautions for use

Adrenal suppression can occur, even without occlusion. The use of occlusive dressings should be avoided because of the increased risk of sensitivity reactions and increased percutaneous absorption. The possibility of sensitivity to neomycin should be taken into consideration especially in the treatment of patients suffering from leg ulcers.

Pregnancy:

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to humans has not been established. However, topical steroids should not be used extensively in pregnancy i.e. in large amounts for long periods. Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Children:

In infants, long term continuous topical steroid therapy should be avoided.

4.5 Interaction with other medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development. The relevance of this finding to humans has not been established. However, topical steroids should not be used extensively in pregnancy i.e. in large amounts for long periods. Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Children:

In infants, long term continuous topical steroid therapy should be avoided.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

General disorders and administration site conditions

Rebound effect – see **Section 4.2 Dose and method of administration.**

Triamcinolone acetonide is well tolerated. Where adverse reactions occur, they are usually reversible on cessation of therapy. However, the following side effects have been reported usually with prolonged usage.

Dermatological: Impaired wound healing, thinning of the skin, petechiae and ecchymoses, facial erythema and telangiectasia, increased sweating, purpura, striae, hirsutism, acneiform eruptions, lumps erythematosus-like lesions and suppressed reactions to skin tests. These effects may be enhanced with occlusive dressings.

Signs of systemic toxicity such as oedema and electrolyte imbalance have not been observed even when high topical dosage has been used. The possibility of the systemic effects which are associated with all steroid therapy should be considered.

Neomycin: Sensitivity reactions may occur especially with prolonged use. Ototoxicity and nephrotoxicity have been reported. Large amounts of this product should be avoided in the treatment of skin infections following excessive burns, trophic ulceration and other conditions where absorption of neomycin is possible.

Gramicidin: Sensitivity has occasionally been reported.

Nystatin: There have been no substantiated reports of sensitivity associated with topical nystatin.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>.

4.9 Overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Triamcinolone acetonide is a potent fluorinated corticosteroid with rapid anti-inflammatory action, anti-pruritic and anti-allergic actions.

The combined action of the antibiotics neomycin and gramicidin provides comprehensive antibacterial therapy against a wide range of Gram-positive and Gram-negative bacteria, including those micro-organisms responsible for most bacterial skin infections.

Nystatin is an antifungal antibiotic, active against a wide range of yeasts and yeast like fungi, including *Candida albicans*.

5.2 Pharmacokinetic properties

Absorption

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 dressing.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption (see **Section 4.4, Special Warnings and Precautions for use**).

Once absorbed through the skin, topical corticosteroids are handled through the same pharmacokinetic pathways as systemically administered corticosteroids.

Metabolism & Excretion

Corticosteroids are metabolised primarily in the liver and are then excreted by the kidneys.

Once absorbed, neomycin is rapidly excreted unchanged through the kidneys.

5.3 Preclinical safety data

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Cetomacrogol
- Citric acid monohydrate
- Dibasic sodium phosphate monohydrate
- Ethanol
- Liquid paraffin
- Methyl hydroxybenzoate
- Perfume 5254
- Propyl hydroxybenzoate
- Propylene glycol
- Purified water
- White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 25 °C.

6.5 Nature and contents of container

15 g tubes.

6.6 Special precautions for disposal

No special precautions.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

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9 DATE OF FIRST APPROVAL

16 May 2002

10 DATE OF REVISION OF THE TEXT

28 March 2022

SUMMARY TABLE OF CHANGES

Date	Section(s) Changed	Change (s)
March 2022	All	Correction of general spacing, typo & grammar errors.
March 2022	4.2, 4.8	Corticosteroid – rebound effect.