

## New Zealand Data Sheet

# Kenacomb Ointment

*Gramicidin, neomycin as sulphate,  
triamcinolone acetonide and nystatin*

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## Presentation

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### *Ointment:*

0.025% **gramicidin**, 0.25% **neomycin**, 100 000U **nystatin**, 0.1% **triamcinolone acetonide**, per g; yellow to amber in Plastibase.

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## Uses

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### *Actions*

Triamcinolone acetonide, a topical corticosteroid has anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of 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 recognisable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Neomycin and gramicidin provide antibacterial activity against microorganisms likely to be responsible for topical bacterial infections.

These ingredients give symptomatic relief of the pain, burning and itching of infected skin, while combating the relevant bacterial and/or monilial infection.

### **Pharmacokinetics**

The extent of percutaneous absorption of topical steroids 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 (see DOSAGE AND ADMINISTRATION).

Once absorbed through the skin, topical corticosteroids are handled through the same pharmacokinetic pathways as systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolised 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.

Nystatin and Gramicidin are not absorbed from intact skin or mucous membranes. Neomycin can be absorbed through inflamed skin. Once absorbed it is rapidly excreted unchanged through the kidneys. The half-life is approximately 2 to 3 hours.

## **Microbiology**

Nystatin acts by binding to steroids in the cell membrane of susceptible species resulting in a change in membrane permeability and the subsequent leakage of intracellular components.

On repeated subculturing with increasing levels of nystatin *Candida albicans* does not develop resistance to nystatin. Generally, resistance to nystatin does not develop during therapy.

Nystatin exhibits no activity against bacteria, protozoa or viruses.

Neomycin exerts its antibacterial activity against a number of gram-negative organisms by inhibiting protein synthesis. It is not active against *Pseudomonas aeruginosa*, and resistant strains of gram-negative bacteria may develop.

Gramicidin exerts its antibacterial activity against many gram-positive organisms by altering cell membrane permeability.

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## **Indications**

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Kenacomb is indicated for the relief of the inflammatory and pruritic manifestations of dermatoses likely to become or which are already infected.

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## **Dosage and Administration**

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### **Adults and Children:**

Apply to the affected areas two to three times daily.

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## Contraindications

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Known hypersensitivity to triamcinolone, neomycin, nystatin or gramicidin.

Ophthalmic use.

Tuberculous lesions and most viral lesions of the skin such as Herpes simplex, but particularly in vaccinia and varicella.

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## Warnings and Precautions

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If sensitivity or irritation develops, use of this medication should be discontinued and appropriate therapy instituted. Hypersensitivity reactions to the anti-infective components may be masked by the presence of a corticosteroid.

Because of the potential hazard of nephrotoxicity and ototoxicity, this medication should not be used in patients with extensive skin damage or other conditions where absorption of neomycin is possible.

The use of occlusive dressing should be avoided because of the increased risk of sensitivity reactions and increased percutaneous absorption particularly of triamcinolone acetonide and neomycin.

As with any antibiotic preparation, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi other than *Candida*. Corticosteroids, furthermore, can enhance microbial infections. Therefore constant observation of the patient is essential. Should superinfection due to nonsusceptible organisms occur, suitable concomitant antimicrobial therapy must be administered. If a favourable response does not occur promptly, application should be discontinued until the infection is adequately controlled by other anti-infective measures.

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycaemia and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas and prolonged use. Therefore, patients receiving a large dose of any potent topical steroid under any condition(s) which may enhance systemic absorption, should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests, and for impairment of thermal

homeostasis. If any of these conditions occur, an attempt should be made to withdraw the drug, to reduce the frequency of application, or substitute a less potent steroid.

Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur requiring supplemental systemic corticosteroids.

### ***Information for Patients***

Patients using this medication should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for skin use only. Avoid contact with your eyes.
2. Patients should be advised not to use this medication for any disorder other than that for which it was prescribed.
3. Even if symptomatic relief occurs within the first few days of treatment, the patient should be advised not to interrupt therapy until the prescribed course of treatment is completed.
4. Patients should report any signs of adverse reactions.
5. The treated skin should not be bandaged, covered or wrapped unless directed by the physician. Do not use tight fitting plastic pants/incontinence garments as these may constitute occlusive dressing.
6. When using this medication in the inguinal area, patients should be advised to apply the preparation sparingly and to wear loosely fitting clothing.
7. Patients should be advised on preventive measures to avoid reinfection.

### ***Laboratory Tests***

If there is a lack of therapeutic response, KOH smears, cultures or other diagnostic methods should be repeated.

A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating hypothalamic-pituitary-adrenal (HPA) axis suppression due to corticosteroid.

### ***Carcinogenesis, Mutagenesis and Impairment of Fertility***

Long-term animal studies have not been performed to evaluate carcinogenic or mutagenic potential, or possible impairment of fertility in males or females.

### ***Pregnancy: CATEGORY D***

Gentamicin and other aminoglycosides cross the placenta. There is evidence of selective uptake of gentamicin by the foetal kidney resulting in damage (probably reversible) to immature nephrons. Eighth cranial nerve damage has also been reported following in-utero exposure to some of the aminoglycosides. Because of their chemical similarity, all aminoglycosides must be considered potentially nephrotoxic and ototoxic to the foetus. It should also be noted that therapeutic blood levels in the mother do not equate with safety for the foetus.

### ***Nursing Mothers:***

It is not known whether topical administration of this medication could result in sufficient systemic absorption of the components to produce detectable quantities in breast milk. Nevertheless caution should be executed when this medication is administered to a nursing woman.

### ***Paediatric Use***

Use of this medication over large surface areas or for prolonged periods in paediatric patients could result in sufficient systemic absorption to produce systemic effects. Paediatric patients may demonstrate greater susceptibility to 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.

When applied to paediatric patients, this medication should be limited to the least amount for the shortest duration compatible with an effective therapeutic regimen. These patients should be closely monitored for signs and symptoms of systemic effects.

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

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## **Adverse Effects**

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Kenacomb is usually well tolerated. The reactions listed, while uncommon, may occur.

The following local adverse reactions are reported infrequently with topical corticosteroids (reactions are listed in approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis,

acneform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and millaria.

Nystatin is well tolerated even with prolonged therapy. Irritation and cases of contact dermatitis have been reported.

Delayed type hypersensitivity reactions have been reported during use of neomycin; sensitisation has been reported following prolonged use. Ototoxicity and nephrotoxicity have been reported when applied to large surfaces or damaged skin.

Sensitivity reactions to gramicidin have been reported.

### **Paediatric Patients:**

Manifestations of adrenal suppression in paediatric 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.

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## **Overdosage**

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

No specific antidote is available, and treatment should be symptomatic.

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## **Pharmaceutical Precautions**

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Store below 25°C.

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## **Medicine Classification**

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Prescription Medicine.

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## **Package Quantities**

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*Ointment*, 15g and 30g.

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## **Further Information**

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**Kenacomb Ointment** is preservative-free, and avoids the risk of allergy to preservatives.

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## **Name and Address**

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## **Date of Preparation**

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22 July 2010