NEW ZEALAND DATA SHEET

1. PRODUCT NAME

KENACOMB OTIC ear drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of KENACOMB OTIC ear drops provides triamcinolone acetonide 0.9 mg, neomycin sulfate 2.25 mg, gramicidin 0.225 mg and nystatin 90,000 IU.

For the list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

KENACOMB OTIC ear drops is an oily, yellow liquid.

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, especially otitis externa.

4.2 Dose and method of administration

Adults and Children:

After cleaning, apply the nozzle to the aural canal and squeeze small amount into the canal two to four times daily.

4.3 Contraindications

- In tuberculous and most topical or systemic viral lesions of the skin, particularly herpes simplex, vaccinia and varicella.
- 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

Care is necessary in applying this preparation if perforation of the eardrum is suspected.

If sensitivity or irritation develops, topical 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.

Aminoglycoside antibiotics may cause irreversible, partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is dose related and is enhanced by renal or hepatic impairment. This possibility should be considered when high doses or prolonged treatment is given to small children.

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, hyperglycemia, 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 steroids 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.

Adrenal suppression can occur.

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.

Not for ophthalmic use.

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 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 the treatment, the patient should be advised not to interrupt or discontinue therapy until the prescribed course of treatment is completed.

4. Patients should report any signs of adverse reactions.

5. The treated skin areas should not be bandaged, covered or wrapped unless directed by the physician.

6. Patients should be advised on preventive measures to avoid reinfection

7. Exercise special care when introducing the cannula tip into the ear.

4.5 Interactions with other medicines and other forms of interaction

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.

4.6 Fertility, pregnancy and lactation

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

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 or for long periods. Topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk of to 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 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.

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.

4.8 Undesirable effects

The following local adverse reactions are reported infrequently with topical corticosteroids (reactions are listed in an approximate decreasing order of occurrence):

burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

Blurred vision has been reported.

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.

Triamcinolone acetonide
Triamcinolone acetonide is well tolerated. Where adverse reactions occur they are usually reversible on cessation of therapy.

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

Gramicidin
Sensitivity reactions have been reported.

Nystatin
Nystatin is well tolerated even with prolonged therapy. Irritation and cases of contact dermatitis 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 papiledema.

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 to https://pophealth.my.site.com/carmreportnz/s/.

4.9 Overdose
Topically applied corticosteroids and neomycin can be absorbed in sufficient amounts to produce systemic effects (see **Undesirable effects**).

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

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

5. PHARMACOLOGICAL PARTICULARS

Actions
KENACOMB OTIC ear drops is intended for application to the external auditory canal.

Triamcinolone acetonide is a potent fluorinated corticosteroid with rapid anti-inflammatory, antipruritic 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 of the external auditory canal.

- Neomycin exerts its anti-bacterial 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.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Plastibase (a proprietary mixture of polyethylene and liquid paraffin).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
18 months.

6.4 Special precautions for storage
Store at 2°C - 8°C (Refrigerate, do not freeze).

6.5 Nature and contents of container
7.5 mL plastic dropper bottle with a dropper nozzle.

6.6 Special precautions for disposal and other handling
No special requirements for disposal.

Instructions for Handling:
Dilution: Not recommended, as this would reduce the concentration of the antibiotics to below therapeutic levels.

7. MEDICINE SCHEDULE

Prescription medicine.

8. SPONSOR

Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics
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9. DATE OF FIRST APPROVAL

2 October 1975

10. DATE OF REVISION OF THE TEXT

4 October 2024

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
1,2,3 & 5	'KENACOMB OTIC ear drops' product name as per product label
2	Change to reflect active quantities to mg/mL instead of mg/g as per product label.
3	Correction.
4.4	Additional safety instruction
4.8	Addition of 'blurred vision' to AE
5	Update to the safety information