NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Kenalog in Orabase oral paste 1 mg/g.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Kenalog in Orabase contains 0.1% triamcinolone acetonide.

For the list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Kenalog in Orabase is an opaque, light brown oral paste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Kenalog in Orabase (triamcinolone acetonide dental paste USP) is indicated for adjunctive treatment and for the temporary relief of symptoms associated with oral inflammatory lesions and ulcerative lesions resulting from trauma.

4.2 Dose and method of administration

Press a small dab (about 6 mm) to the lesion until a thin film develops. A larger quantity may be required for coverage of some lesions. For optimal results use only enough to coat the lesion with a thin film. Do not rub in. Attempting to spread this preparation may result in a granular, gritty sensation and cause it to crumble. After application, however, a smooth, slippery film develops.

The preparation should be applied at bedtime to permit steroid contact with the lesion throughout the night. Depending on the severity of symptoms, it may be necessary to apply the preparation two or three times a day, preferably after meals. If significant repair or regeneration has not occurred in seven days, further investigation is advisable.

4.3 Contraindications

This preparation is contraindicated in patients with a history of hypersensitivity to any of its components. Because it contains a corticosteroid, the preparation is contraindicated in the presence of fungal, viral, or bacterial infections of the mouth or throat. It should not be used in herpetic lesions of known viral origin such as Herpes labialis or intraoral lesions such as primary herpetic gingival stomatitis and herpanginas.

4.4 Special warnings and precautions for use

Patients with tuberculosis, peptic ulcer or diabetes mellitus should not be treated with any corticosteroid preparation without the advice of the patient's physician. It should be borne in mind that the normal defensive responses of the oral tissues are depressed in patients receiving topical corticosteroid therapy. Virulent strains of oral micro-organisms may multiply without producing the usual warning symptoms of oral infections.

The small amount of steroid released when the preparation is used as recommended makes systemic effects very unlikely; however, they are a possibility when topical corticosteroid preparations are used over a long period of time and any unusual symptoms such as weakness or dizziness should be called to the physician's attention by the patient.

If local irritation or sensitisation should develop, the preparation should be discontinued and appropriate therapy instituted.

If significant regeneration or repair of oral tissues has not occurred in seven days, additional investigation into the aetiology of the oral lesion is advised.

4.5 Interactions with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Safe use of this preparation during pregnancy has not been established with respect to possible adverse reactions upon foetal development; therefore it should not be used in women of child-bearing potential and particularly during early pregnancy unless in the judgement of the physician or dentist the potential benefits outweigh the possible hazards.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

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://nzphvc.otago.ac.nz/reporting/.

Prolonged administration may elicit the adverse reactions known to occur with systemic steroid preparations; for example adrenal suppression, alteration of glucose metabolism, protein catabolism, peptic ulcer activations, and others. These are usually reversible and disappear when the hormone is discontinued.

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

Actions
Kenalog in Orabase (triamcinolone acetonide) is a synthetic corticosteroid which possess anti-inflammatory antipruritic, and anti-allergic action which may provide prompt relief of oral tenderness, pain, inflammation and ulceration. The emollient dental paste is an adhesive vehicle for applying medication to the oral surfaces. This adhesive maintains the medication in close contact with the lesion and provides a protective covering which augments the effects of the steroid.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin, pectin and carmellose sodium in Plastibase® (Plastibase hydrocarbon gel - a polyethylene and mineral oil gel base).

6.2 Incompatibilities

Not relevant.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 25^{o}C. Keep tube tightly closed.

6.5 Nature and contents of container

5 g tube. Packs of 1.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. MEDICINE SCHEDULE

Prescription Medicine.

(≤ 5 g Restricted Medicine)

8. SPONSOR

Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland, New Zealand

Telephone: (09) 918 5100
Email: aspen@aspenpharma.co.nz

9. DATE OF REVISION OF THE TEXT

5 April 2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
	Update to the SPC-style.