AUSTRALIAN PRODUCT INFORMATION

KENALOG IN ORABASE
(triamcinolone acetonide) paste

1 NAME OF THE MEDICINE

Triamcinolone acetonide.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of Kenalog in Orabase provides 1 mg (0.1%) triamcinolone acetonide.

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

3 PHARMACEUTICAL FORM

An opaque light brown ointment.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Acute and chronic lesions of the oral mucosa including recurrent ulcerative aphthous stomatitis; Erosive lichen planus; denture stomatitis; traumatic lesions including denture sore spots; desquamative gingivitis and stomatitis. Lesions of traumatic origin and most nonrecurring conditions heal rapidly and permanently. Chronic and recurrent lesions are promptly relieved, but symptoms usually recur after termination of therapy. However, Kenalog in Orabase is effective in suppressing subsequent recurrences.

4.2 DOSE AND METHOD OF ADMINISTRATION

Press a small dab (about 1 cm) 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 2 or 3 times a day, preferably after meals.

4.3 CONTRAINDICATIONS

Patients with a history of hypersensitivity to any of its components. Because it contains a corticosteroid, it is contraindicated in the presence of fungal 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

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.

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 microorganisms may multiply without producing the usual warning symptoms of oral infections.

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

Use in the elderly
No data available.

Paediatric use
No data available.

Effects on laboratory tests
No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility
No data available.

Use in pregnancy – Pregnancy Category C
Safe use of this preparation during pregnancy has not been established with respect to possible adverse reactions upon fetal development. Use during pregnancy is not recommended unless the physician or dentist feels that the benefits outweigh the risks.

In animal experiments, corticosteroids have been found to cause malformations of various kinds (cleft palate, skeletal malformations) and abortion. These findings do not seem to be relevant to humans. Reduced placental and birth weight have been recorded in humans after long-tern treatment. Since the possibility of suppression of the adrenal cortex in the newborn baby after long-term treatment must be considered, the needs of the mother must be carefully weighed against the risk to the fetus when prescribing these drugs. The short-term use of corticosteroids antepartum for the prevention of respiratory distress syndrome does not seem to pose a risk for the newborn infant. Maternal pulmonary oedema has been reported with tocolysis and fluid overload.

Use in lactation
No data available.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Reporting suspected adverse effects
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

Intolerance to the preparation is extremely rare. No topical reactions to the corticosteroid have been observed with intraoral application.

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 information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action
Kenalog is a corticosteroid with anti-inflammatory, antipruritic and antiallergic 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.

Clinical trials
No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Gelatin, pectin, carmellose sodium and plastibase (a plasticised hydrocarbon gel - a polyethylene and mineral oil gel base).

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25ºC.

6.5 NATURE AND CONTENTS OF CONTAINER

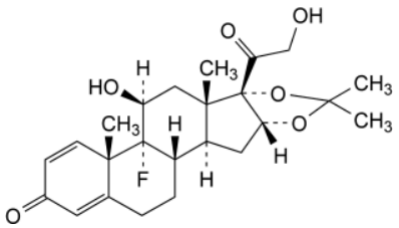
5 g dental paste in a sealed aluminium tube.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



CAS number

76-25-5

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 3 – Pharmacist Only Medicine

8 SPONSOR

Aspen Pharma Pty Ltd
34-36 Chandos Street,
St. Leonards NSW 2065
Australia

http://www.aspenpharma.com.au

9 DATE OF FIRST APPROVAL

30/09/1991

10 DATE OF REVISION

10 July 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Updated to the revised Australian product information format and content.
8	Addition of Aspen website.