1 ORACORT

Triamcinolone acetonide dental paste USP, 0.1%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oracort contains 0.1% triamcinolone acetonide

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral paste

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Triamcinolone Acetonide Dental Paste USP is indicated for adjunctive treatment and for the temporary relief of symptoms associated with oral inflammatory lesions resulting from trauma.

4.2 Dose and method of administration

Press a small dab (about 6mm) 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 to 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 contra-indicated 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.

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 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.

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

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

4.5 Interaction with other medicines and other forms of interaction

Not applicable.

4.6 Fertility, pregnancy and lactation

Safe use of this product during pregnancy has not been established with respect to possible adverse reactions on 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 applicable.

4.8 Undesirable effects

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.

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

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 synthetic corticosteroid which possesses anti- inflammatory anti-pruritic, 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 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.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium
Gelatin
Liquid paraffin
Pectin
Polyethylene

6.2 Incompatibilities

None.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Store below 30°C. Keep tube tightly closed.

6.5 Nature and contents of container

5g tube.

6.6 Special precautions for disposal

No special requirements for disposal

7 MEDICINE SCHEDULE

Restricted medicine

8 SPONSOR

AFT Pharmaceuticals Ltd
PO Box 33.203
Takapuna
Auckland
Email:customer.service@aftpharm.com

9 DATE OF FIRST APPROVAL

18/03/1999

10 DATE OF REVISION OF THE TEXT

October 2018

SUMMARY TABLE OF CHANGES

Date	Section(s) Changed	Change (s)
October 2018	All	Reformat consistent with new Medsafe Data Sheet Template.