PRESCRIBING INFORMATION

PrKENALOG in ORABASE

(triamcinolone Dental Paste))

Dental Corticosteroid

Bristol-Myers Squibb Canada
2365 Côte-de-Liesse
Montreal, Canada H4N 2M7

Date of Preparation:
November 19, 2004

* TM of Bristol-Myers Squibb Canada

Date of Revision:

Control No.: 095318

PRESCRIBING INFORMATION

PrKENALOG in ORABASE
(Triamcinolone Dental Paste)

THERAPEUTIC CLASSIFICATION

Dental Corticosteroid

ACTION AND CLINICAL PHARMACOLOGY

Triamcinolone is a synthetic corticosteroid which possesses anti-inflammatory, antipruritic, and antiallergic action. The emollient dental paste acts as an adhesive vehicle for applying the active medication to the oral tissues. The vehicle provides a protective covering which may serve to temporarily reduce the pain associated with oral irritation.

INDICATIONS AND CLINICAL USE

Adjunctive treatment and temporary relief of symptoms associated with oral inflammatory lesions and ulcerative lesions resulting from trauma.

CONTRAINDICATIONS

Fungal, viral or bacterial infections of the mouth or throat. Hypersensitivity to any of the components.

PRECAUTIONS

Pregnancy: Safe use of this preparation during pregnancy has not been established with respect to possible adverse reactions upon fetal development; therefore, it should not be used in women of childbearing potential and particularly during early pregnancy unless the potential benefits outweigh the possible hazards.

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 reponses of the oral tissues are depressed in patients receiving topical corticosteroid therapy. Virulent strains of oral microorganisms may multiply without producing the usual 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, discontinue the preparation and institute appropriate therapy.

ADVERSE REACTIONS

Prolonged administration may elicit the adverse reactions known to occur with systemic steroid preparations; e.g., adrenal suppression, alteration of glucose metabolism, protein catabolism, peptic

ulcer activation and others. These are usually reversible and disappear when the hormone is discontinued.

DOSAGE AND 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.

Apply 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. If significant regeneration or repair of oral tissues has not occurred in 7 days, additional investigation into the etiology of the oral lesion is advised.

AVAILABILITY OF DOSAGE FORMS

Each gram of KENALOG in ORABASE contains 1 mg (0.1%) of triamcinolone acetonide.

Nonmedicinal ingredients

- Orabase (protective emollient vehicle) contains gelatin, pectin and sodium carboxymethylcellulose.
- Plastibase (plasticized hydrocarbon gel) contains mineral oil and polyethylene.

Tubes of 7.5 g. Keep tightly closed.