

## **KENALOG® IN ORABASE®**

**(Triamcinolone Acetonide Dental Paste, USP), 0.1%**

**Rx only**

### **DESCRIPTION**

**KENALOG® IN ORABASE® (Triamcinolone Acetonide Dental Paste, USP), 0.1%, contains the corticosteroid triamcinolone acetonide in an adhesive vehicle suitable for application to oral tissues. Triamcinolone acetonide is designated chemically as 9-fluoro-11β, 16α, 17, 21-tetrahydroxypregna-1,**

**4-diene-3, 20-dione cyclic 16, 17-acetal with acetone. The structural formula of triamcinolone acetonide is as follows:**

*[Picture of structural formula will be placed here]*

C<sub>24</sub>H<sub>31</sub>FO<sub>6</sub>, MW 434.50

Each gram of KENALOG® IN ORABASE® contains 1 mg triamcinolone acetonide in a dental paste containing gelatin, pectin, and carboxymethylcellulose sodium in Plastibase® (Plasticized Hydrocarbon Gel), a polyethylene and mineral oil gel base.

### **CLINICAL PHARMACOLOGY**

**Like other topical corticosteroids, triamcinolone acetonide has anti-inflammatory, antipruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A<sub>2</sub> inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A<sub>2</sub>.**

### **Pharmacokinetics**

**The extent of absorption through the oral mucosa is determined by multiple factors including the vehicle, the integrity of the mucosal barrier, the duration of therapy, and the presence of inflammation and/or other disease processes. Once absorbed through the mucous membranes, the disposition of corticosteroids is similar to that of systemically administered corticosteroids. Corticosteroids are bound to the plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys; some corticosteroids and their metabolites are also excreted into the bile.**

### **INDICATIONS AND USAGE**

**KENALOG® IN ORABASE® (Triamcinolone Acetonide Dental Paste, USP), 0.1% is indicated for adjunctive treatment and for the temporary relief of symptoms associated with oral inflammatory lesions and ulcerative lesions resulting from trauma.**

### **CONTRAINDICATIONS**

**KENALOG® IN ORABASE® is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations; it is also contraindicated in the presence of fungal, viral, or bacterial infections of the mouth or throat.**

## PRECAUTIONS

### General:

KENALOG® IN ORABASE® may cause local adverse reactions. If irritation develops, KENALOG® IN ORABASE® should be discontinued and appropriate therapy instituted. Allergic contact sensitization with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

**If concomitant mucosal infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of KENALOG® IN ORABASE® should be discontinued until the infection has been adequately controlled.**

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

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, glucosuria, and other adverse effects known to occur with parenterally-administered steroid preparations; therefore, it may be advisable to periodically evaluate patients on prolonged therapy with corticosteroid-containing dental pastes for evidence of HPA axis suppression (see **PRECAUTIONS, Laboratory Tests**). If HPA axis suppression is noted, an attempt should be made to withdraw the drug or to reduce the frequency of application. Recovery of HPA axis function is generally prompt and complete upon discontinuation of therapy.

**Information for the Patient:** Patients using topical corticosteroids should receive the following information and instructions:

**This medication is to be used as directed by the physician or dentist. It is for oral use only; it is not intended for ophthalmic or dermatological use.**

**Patients should be advised not to use this medication for any disorder other than for which it was prescribed.**

**Patients should report any signs of adverse reactions.**

**As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, contact the physician or dentist.**

#### **Laboratory Tests**

A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

#### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Animal studies have not been performed to evaluate triamcinolone acetonide for potential to induce carcinogenesis, mutagenesis, or impairment of fertility.

**Pregnancy Category C:** Teratogenic effects. Triamcinolone acetonide has been shown to induce teratogenic effects in several species. In mice and rabbits, triamcinolone acetonide induced an increased incidence of cleft palate at dosages of approximately 120 µg/kg/day and 24 µg/kg/day, respectively (approximately 12 times and 10 times the amount in a typical daily human dose of KENALOG<sup>®</sup> IN ORABASE<sup>®</sup> when compared following normalization of the data on the basis of body surface area estimates, respectively). In monkeys, triamcinolone acetonide induced cranial skeletal malformations at the lowest dosage studied (500 µg/kg/day), which was approximately 200 times the amount in a typical daily human dose of KENALOG<sup>®</sup> IN ORABASE<sup>®</sup> when compared following normalization of the data on the basis of body surface area estimates. There are no adequate and well-controlled studies in pregnant women. However, a retrospective analysis of birth defects among children born to mothers that used drugs of the same class as KENALOG<sup>®</sup> IN ORABASE<sup>®</sup> (corticosteroids) during pregnancy found an approximately 3 times increased incidence of cleft palate. KENALOG<sup>®</sup> IN ORABASE<sup>®</sup> should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### **Nursing Mothers**

It is not known whether oral application of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when corticosteroid-containing dental pastes are prescribed for a nursing woman.

#### **Pediatric Use**

The safety and efficacy of KENALOG<sup>®</sup> IN ORABASE<sup>®</sup> in children is unknown. Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's Syndrome than mature patients because of a larger skin surface area to body weight ratio. Administration of corticosteroid-containing dental pastes to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

#### **Geriatric Use**

Clinical studies of KENALOG<sup>®</sup> IN ORABASE<sup>®</sup> did not include sufficient numbers of subjects age 65 and older to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

#### **ADVERSE REACTIONS**

The following local adverse reactions may occur with corticosteroid-containing dental pastes: burning, itching, irritation, dryness, blistering or peeling not present prior to therapy, perioral dermatitis, allergic contact dermatitis, maceration of the oral mucosa, secondary infection, and atrophy of the oral mucosa.

Also, see **PRECAUTIONS** for potential effects of systemic absorption.

#### **DOSAGE AND ADMINISTRATION**

Press a small dab (about 1/4 inch) 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 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.

#### **HOW SUPPLIED**

KENALOG® IN ORABASE® (Triamcinolone Acetonide Dental Paste, USP), 0.1%  
Tubes containing 5 g of dental paste                      NDC 0003-0496-20

#### **Storage**

Keep tightly closed. Store at controlled room temperature, 15° - 25° C (59° - 77° F).

**APOTHECON®**

A Bristol-Myers Squibb Company  
Princeton, NJ 08540 USA

TUBE

Back Side

Each gram contains 1 mg triamcinolone acetonide (0.1%) in emollient dental paste composed of gelatin, pectin and carboxymethyl-cellulose sodium in Plastibase (Plasticized Hydrocarbon Gel), a polyethylene and mineral oil gel base.

**FOR TOPICAL USE IN  
ADJUNCTIVE TREATMENT OF  
ORAL LESIONS**

Usual dose: Apply thin film to affected area, preferably at bedtime- See insert.

**Keep tightly closed.**

Store at controlled room temperature,  
15° – 25° C (59° – 77 ° F).

APOTHECON  
A Bristol-Myers Squibb Company  
Princeton, NJ 08540 USA  
D2273L/49620

TUBE

In between

Front and back of tube

To open:  
Pierce sealed  
end with a  
point  
Exp.  
Date and  
Control  
On crimp

TUBE

Front Side

5 grams NDC 0003-0496-20

KENALOG  
IN ORABASE  
Triamcinolone  
Acetonide  
Dental Paste, USP, 0.1%

**Rx only**

**Read all sides**

APOTHECON  
logo here

CARTON  
Back Side

CARTON  
In between  
Front and back of tube

CARTON  
Front Side

KENALOG  
IN ORABASE  
Triamcinolone  
Acetonide  
Dental Paste, USP, 0.1%

Each gram contains 1 mg  
triamcinolone acetonide  
(0.1%) in emollient dental paste  
composed of gelatin, pectin and  
carboxymethyl-cellulose sodium  
in Plastibase (Plasticized Hydro-  
carbon Gel), a polyethylene and  
mineral oil gel base.

UPC  
Barcode for  
NDC  
number

5 grams NDC 0003-0496-20

KENALOG  
IN ORABASE  
Triamcinolone  
Acetonide  
Dental Paste, USP, 0.1%

**FOR TOPICAL USE IN  
ADJUNCTIVE TREATMENT OF  
ORAL LESIONS**

**Rx only**

**Read all sides**

Usual dose: Apply thin film to  
affected area, preferably at  
bedtime- See insert.

**Keep tightly closed.**

Store at controlled room  
temperature,  
15° – 25° C (59° – 77 ° F).

APOTHECON  
A Bristol-Myers Squibb Company  
Princeton, NJ 08540 USA  
L6146L/49620

APOTHECON  
logo here

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For current labeling information, please visit <https://www.fda.gov/drugsatfda>

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Jonathan Wilkin  
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