**KENALOG®-10 INJECTION**  
(triamcinolone acetonide injectable suspension, USP)

**NOT FOR USE IN NEONATES**  
CONTAINS BENZYL ALCOHOL

For Intra-articular or Intralesional Use Only

**NOT FOR INTRAVENOUS, INTRAMUSCULAR, INTRAOCULAR, EPIDURAL, OR INTRATHECAL USE**

**DESCRIPTION**

Kenalog®-10 Injection (triamcinolone acetonide injectable suspension, USP) is a synthetic glucocorticoid corticosteroid with marked anti-inflammatory action, in a sterile aqueous suspension suitable for intralesional and intra-articular injection. THIS FORMULATION IS SUITABLE FOR INTRA-ARTICULAR AND INTRALESIONAL USE ONLY.

Each mL of the sterile aqueous suspension provides 10 mg triamcinolone acetonide, with 0.66% sodium chloride for isotonicity, 0.99% (w/v) benzyl alcohol as a preservative, 0.63% carboxymethylcellulose sodium, and 0.04% polysorbate 80. Sodium hydroxide or hydrochloric acid may have been added to adjust pH between 5.0 and 7.5. At the time of manufacture, the air in the container is replaced by nitrogen.

The chemical name for triamcinolone acetonide is 9-Fluoro-11β,16α,17, 21-tetrahydroxy-pregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone. Its structural formula is:

![Chemical structure of triamcinolone acetonide](image)

**CLINICAL PHARMACOLOGY**

Glucocorticoids, naturally occurring and synthetic, are adrenocortical steroids that are readily absorbed from the gastrointestinal tract.

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Synthetic analogs such as triamcinolone are primarily used for their anti-inflammatory effects in disorders of many organ systems.

**INDICATIONS AND USAGE**

The intra-articular or soft tissue administration of Kenalog-10 Injection (triamcinolone acetonide injectable suspension, USP) is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, inflammatory effects in disorders of many organ systems.

The intra-articular or soft tissue administration of Kenalog-10 Injection is indicated for alopecia areata; discoid lupus erythematosus, acute and subacute bullous, acute non-specific tenosynovitis, epicondylitis, rheumatoid arthritis, synovitis, or osteoarthritis.

The intraleisonal administration of Kenalog-10 Injection is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflamatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabietorum. Kenalog-10 Injection may also be useful in cystic tumors of an aperoneosis or tendon (ganglia).

**CONTRAINdications**

Kenalog-10 Injection is contraindicated in patients who are hypersensitive to any components of this product (see WARNINGS: General).

Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura.

**WARNINGS**

Serious Neurologic Adverse Reactions with Epidural Administration

Serious neurologic events, some resulting in death, have been reported with epidural injection of corticosteroids (see WARNINGS: Neurologic). Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. The safety and effectiveness of epidural administration of corticosteroids have not been established, and corticosteroids are not approved for this use.

**General**

Exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates, and an increased incidence of kernicterus, particularly in small preterm infants. There have been rare reports of deaths, primarily in preterm infants, associated with exposure to excessive amounts of benzyl alcohol. The amount of benzyl alcohol from medications is usually considered negligible compared to that received in flush solutions containing benzyl alcohol. Administration of high dosages of medications containing this preservative must take into account the total amount of benzyl alcohol administered. The amount of benzyl alcohol at which toxicity may occur is not known. If the patient requires more than the recommended dosages or other medications containing this preservative, the practitioner must consider the daily metabolic load of benzyl alcohol from these combined sources (see PRECAUTIONS: Pediatric Use).

Because Kenalog-10 Injection (triamcinolone acetonide injectable suspension, USP) is a suspension, it should not be administered intravenously. Strict aseptic technique is mandatory.

Rare instances of anaphylaxis have occurred in patients receiving corticosteroid therapy (see ADVERSE REACTIONS). Cases of serious anaphylaxis, including death, have been reported in individuals receiving triamcinolone acetonide injection, regardless of the route of administration.

Increased dosage of rapidly acting corticosteroids is indicated in patients on corticosteroid therapy subjected to any unusual stress before, during, and after the stressful situation.

Kenalog-10 Injection is a long-acting preparation, and is not suitable for use in acute stress situations.

Results from one multicenter, randomized, placebo-controlled study with methylprednisolone hemisuccinate, an intravenous corticosteroid, showed an increase in early (at 2 weeks) and late (at 6 months) mortality in patients with cranial trauma who were determined not to have other clear indications for corticosteroid treatment. High doses of systemic corticosteroids, including Kenalog-10 Injection, should not be used for the treatment of traumatic brain injury.

**Cardio-Renal**

Average and large doses of corticosteroids can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when they are used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

Literature reports suggest an apparent association between use of corticosteroids and left ventricular free wall rupture after a recent myocardial infarction; therefore, therapy with corticosteroids should be used with great caution in these patients.

**Endocrine**

Corticosteroids can produce reversible hypothalamic-pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment.

Metabolic clearance of corticosteroids is decreased in hypothyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in dosage.

**Infections**

**General**

Patients who are on corticosteroids are more susceptible to infections than are healthy individuals. There may be decreased resistance and inability to localize infection when corticosteroids are used. Infection with any pathogen (viral, bacterial, fungal, protozoan, or helminthic) in any location of the body may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents. These infections may be mild to severe. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases. Corticosteroids may also mask some signs of current infection.

**Fungal Infections**

Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control drug reactions. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure (see PRECAUTIONS: Drug Interactions: Amphotericin B injection and potassium-depleting agents).

**Special Pathogens**

Serious disease may be latent or there may be an exacerbation of intercurrent infections due to pathogens, including those caused by Amoeba, Candida, Cryptococcus, Mycobacterium, Nocardia, Pneumocystis, or Toxoplasma. It is recommended that latent amebiasis or active amebiasis be ruled out before initiating corticosteroid therapy in any patient who has spent time in the tropics or in any patient with unexplained diarrhea.

Similarly, corticosteroids should be used with great care in patients with known or suspected Strongyloides (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicaemia.

Corticosteroids should not be used in cerebral malaria.
Tuberculosis
If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Vaccination
Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered. However, the response to such vaccines cannot be predicted. Immunization procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, eg, for Addison’s disease.

Viral Infections
Chicken pox and measles can have a more serious or even fatal course in pediatric and adult patients on corticosteroids. In pediatric and adult patients who have not had these diseases, particular care should be taken to avoid exposure. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chicken pox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chicken pox develops, treatment with antiviral agents should be considered.

Neurologic
Epidural and intrathecal administration of this product is not recommended. Reports of serious medical events, including death, have been associated with epidural and intrathecal routes of corticosteroid administration (see ADVERSE REACTIONS: Gastrointestinal and Neurologic/Psychiatric).

Ophthalmic
Use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. The use of oral corticosteroids is not recommended. In the treatment of optic neuritis and may lead to an increase in the risk of new episodes. Corticosteroids should not be used in active ocular herpes simplex.

Adequate studies to demonstrate the safety of Kenalog Injection use by intrabulbar, subconjunctival, sub-Tenons, retrobulbar, and intracocular (intravitreal) injections have not been performed. Endophthalmitis, eye inflammation, increased intraocular pressure, and visual disturbances including vision loss have been reported with intravitreal administration. Administration of Kenalog Injection intracocularly or into the nasal turbinates is not recommended.

Intracocular injection of corticosteroid formulations containing benzyl alcohol, such as Kenalog Injection, is not recommended because of potential toxicity from the benzyl alcohol.

PRECAUTIONS
General
This product, like many other steroid formulations, is sensitive to heat. Therefore, it should not be autoclaved when it is desirable to sterilize the exterior of the vial.

The lowest possible dose of corticosteroid should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual.

Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used.

Kaposi’s sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement.

Cardio-Renal
As sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency.

Endocrine
Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

Gastrointestinal
Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis, since they may increase the risk of a perforation.

Signs of peritoneal irritation following gastrointestinal perforation in patients receiving corticosteroids may be minimal or absent.

There is an enhanced effect of corticosteroids in patients with cirrhosis.
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**Antidiabetics:** Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.

**Antibacterial drugs:** Serum concentrations of isoniazid may be decreased.

**Cholestryamine:** Cholestryamine may increase the clearance of corticosteroids.

**Cyclosporine:** Increased activity of both cyclosporine and corticosteroids may occur when these are used concurrently. Convulsions have been reported with this concurrent use.

**Digitalis glycosides:** Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia.

**Estrogens:** Including oral contraceptives: Estrogens may decrease the hepatic metabolism of certain corticosteroids, thereby increasing their effect.

**Hepatic enzyme inducers (eg, barbiturates, phenytoin, carbamazepine, rifampin):** Drugs which induce hepatic microsomal drug metabolizing enzyme activity may enhance the metabolism of corticosteroids and require that the dosage of the corticosteroid be increased.

**Ketoconazole:** Ketoconazole has been reported to decrease the metabolism of certain corticosteroids by up to 60%, leading to an increased risk of corticosteroid side effects.

**Nonsteroidal anti-inflammatory drugs (NSAIDs):** Concomitant use of aspirin (or other nonsteroidal anti-inflammatory drugs) and corticosteroids increases the risk of gastrointestinal side effects. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprolactinemia. The clearance of salicylates may be increased with concurrent use of corticosteroids.

**Skin tests:** Corticosteroids may suppress reactions to skin tests.

**Vaccines:** Patients on prolonged corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response. Corticosteroids may also potentiate the replication of some organisms contained in live attenuated vaccines. Routine administration of vaccines or toxoids should be deferred until corticosteroid therapy is discontinued if possible (see WARNINGS: Infections: Vaccination).

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

No adequate studies have been conducted in animals to determine whether corticosteroids have a potential for carcinogenesis or mutagenesis.

**Steroids may increase or decrease motility and number of spermatozoa in some patients.**

**Pregnancy**

Teratogenic Effects: Pregnancy Category C

Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate equivalent to the human dose. Animal studies in which corticosteroids have been given during pregnancy should be carefully observed for signs of hypoadrenalism.

**Nursing Mothers**

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

**Pediatric Use**

This product contains benzyl alcohol as a preservative. Benzyl alcohol, a component of this product, has been associated with serious adverse events and death, particularly in newborn infants, as well as patients receiving high dosages, may be more likely to develop toxicity. Practitioners administering this and other medications containing benzyl alcohol should consider the combined daily metabolic load of benzyl alcohol from all sources.

The efficacy and safety of corticosteroids in the pediatric population are based on the well-established course of effect of corticosteroids which is similar in pediatric and adult populations. Published studies provide evidence of efficacy and safety in pediatric patients for the treatment of nephrotic syndrome (>2 years of age), and aggressive lymphomas and leukemias (>1 month of age). Other indications for pediatric use of corticosteroids, eg, severe asthma and wheezing, are based on adequate and well-controlled trials conducted in adults, on the premises that the course of the disease and their pathophysiology are considered to be substantially similar in both populations.

The adverse effects of corticosteroids in pediatric patients are similar to those in adults (see ADVERSE REACTIONS). Like adults, pediatric patients should be carefully observed with frequent measurements of blood pressure, weight, height, intracranial pressure, and clinical evaluation for the presence of infection, psychosocial disturbances, thromboembolism, peptic ulcers, cataracts, and osteoporosis. Pediatric patients who are treated with corticosteroids by any route, including systemically administered corticosteroids, may experience a decrease in their growth velocity. This negative impact of corticosteroids on growth has been observed at low systemic doses and in the absence of laboratory evidence of HPA axis suppression (ie, cosynotropin stimulation and basal cortisol plasma levels). Growth velocity may therefore be a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA axis function. The linear growth of pediatric patients treated with corticosteroids should be monitored, and the potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the availability of treatment alternatives. In order to minimize the potential growth effects of corticosteroids, pediatric patients should be titrated to the lowest effective dose.

**Geriatric Use**

No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

**ADVERSE REACTIONS**

(listed alphabetically under each subsection)

The following adverse reactions may be associated with corticosteroid therapy:

**Allergic reactions:** Anaphylaxis including death, angioedema.

**Cardiovascular:** Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction (see WARNINGS), pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis.

**Dermatologic:** Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, impaired wound healing, increased sweating, lupus erythematosus-like lesions, purpura, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria.

**Endocrine:** Decreased carbohydrate and glucose tolerance, development of cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, manifestations of latent diabetes mellitus, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients.

**Fluid and electrolyte disturbances:** Congestive heart failure in susceptible patients, fluid retention, hypokalemia alkalosis, potassium loss, sodium retention.

**Gastrointestinal:** Abdominal distention, bowel/bladder dysfunction (after intrathecal administration [see WARNINGS: Neurologic]), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis.

**Metabolic:** Negative nitrogen balance due to protein catabolism.

**Musculoskeletal:** Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular or intraosseous use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, post injection flare (following intra-articular use), steroid myopathy, tendon rupture, vertebral compression fractures.

**Neurologic/Psychiatric:** Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebi) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychiatric disorders, vertigo. Adrenocorticosteroids, methadone, paraparesis/paraplegia and sensory disturbances have occurred after intrathecal administration. Spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke (including brainstem) have been reported after epidural administration of corticosteroids (see WARNINGS: Serious Neurologic Adverse Reactions with Epidural Administration and WARNINGS: Neurologic).

**Ophthalmic:** Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, rare instances of blindness associated with pericocular injections.

**Other:** Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.
OVERDOSE
Treatment of acute overdosage is by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of the corticosteroid may be reduced only temporarily, or alternate day treatment may be introduced.

DOSEAGE AND ADMINISTRATION

General
NOTE: CONTAINS BENZYL ALCOHOL (see PRECAUTIONS).
IT SHOULD BE EMPHASIZED THAT DOSAGE REQUIREMENTS ARE VARIABLE AND MUST BE INDIVIDUALIZED ON THE BASIS OF THE DISEASE UNDER TREATMENT AND THE RESPONSE OF THE PATIENT. After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage which will maintain an adequate clinical response is reached. Situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient’s individual drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment. In this latter situation it may be necessary to increase the dosage of the corticosteroid for a period of time consistent with the patient’s condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

For pediatric patients, the initial dose of triamcinolone may vary depending on the specific disease entity being treated. The range of initial doses is 0.11 to 1.6 mg/kg/day in 3 or 4 divided doses (3.2 to 48 mg/m²/bsa/day).

For the purpose of comparison, the following is the equivalent milligram dosage of the various glucocorticoids:

<table>
<thead>
<tr>
<th>Glucocorticoid</th>
<th>Equivalent Triamcinolone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortisone, 25</td>
<td>Triamcinolone, 4</td>
</tr>
<tr>
<td>Hydrocortisone, 20</td>
<td>Prednisolone, 5</td>
</tr>
<tr>
<td>Prednisolone, 5</td>
<td>Dexamethasone, 0.75</td>
</tr>
<tr>
<td>Methylprednisolone, 4</td>
<td>Betamethasone, 0.75</td>
</tr>
</tbody>
</table>

These dose relationships apply only to oral or intravenous administration of these compounds. When these substances or their derivatives are injected intramuscularly or into joint spaces, their relative properties may be greatly altered.

Intra-Articular Administration

Dosage
The initial dose of Kenalog-10 Injection for intra-articular administration may vary from 2.5 mg to 5 mg for smaller joints and from 5 mg to 15 mg for larger joints, depending on the specific disease entity being treated. Single injections into several joints, up to a total of 20 mg or more, have been given.

Intralesional
For intralesional administration, the initial dose per injection site will vary depending on the specific disease entity and lesion being treated. The site of injection and volume of injection should be carefully considered due to the potential for cutaneous atrophy.

Multiple sites separated by one centimeter or more may be injected, keeping in mind that the greater the total volume employed the more corticosteroid becomes available for systemic absorption and systemic effects. Such injections may be repeated, if necessary, at weekly or less frequent intervals.