Product Monograph

Including Patient Medication Information

PrKENALOG®-10 INJECTION

triamcinolone acetonide injection

Injectable Suspension, 10 mg / mL, Intra-Articular, Intradermal

USP

Corticosteroid

Bristol-Myers Squibb Canada

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RECENT MAJOR LABEL CHANGES

4 DOSAGE AND ADMINISTRATION, 4.4 Administration	06/2024
7 WARNINGS AND PRECAUTIONS, Ophthalmologic	08/2023

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

KENALOG-10 INJECTION (triamcinolone acetonide) is indicated for:

- Intra-articular: For intra-articular or intrabursal administration, and for injections into tendon sheaths, as adjunctive therapy for short-term administration in the following conditions: synovitis of osteoarthritis, rheumatoid arthritis, acute and subacute bursitis, acute gouty arthritis, epicondylitis, acute nonspecific tenosynovitis, and post-traumatic osteoarthritis.
- Intradermal: Intralesional administration is indicated for the treatment of keloids, discoid lupus erythematosus, necrobiosis lipoidica diabeticorum, alopecia areata, and localized hypertrophic, infiltrated, inflammatory lesions of lichen planus, psoriatic plaques, granuloma annulare, and lichen simplex chronicus (neurodermatitis).

1.1 Pediatrics

Pediatrics (<18 years of age): KENALOG-10 INJECTION is not for use in newborn or preterm infants. This preparation is not recommended for children under 6 years of age.

1.2 Geriatrics

Geriatrics (≥65 years of age): The common adverse effects of systemic corticosteroids such as osteoporosis or hypertension may be associated with more serious consequences in old age. Close clinical supervision is recommended

2 CONTRAINDICATIONS

- KENALOG-10 INJECTION is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, (see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING**)**
- Corticosteroids are generally contraindicated in patients with systemic infections.
- The preparation should not be injected into infected areas.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- NOTE: KENALOG-10 INJECTION is triamcinolone acetonide, a synthetic glucocorticoid corticosteroid with marked anti-inflammatory action, in a sterile aqueous suspension suitable for intradermal, intra-articular, and intrabursal injection and for injection into tendon sheaths. **This formulation is not suitable for intravenous, intramuscular, intraocular, epidural, or intrathecal injection.**
- This preparation contains benzyl alcohol. Not for use in newborn or premature infants, (see 7.1.3 WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics), when injected intradermally.

4.2 Recommended Dose and Dosage Adjustment

- Intra-articular or intrabursal and tendon sheaths: The initial dose of KENALOG-10 INJECTION for intra-articular or intrabursal administration and for injection into tendon sheaths may vary from 2.5 to 5 mg (0.25 to 0.5 mL) for smaller joints and from 5 to 15 mg (0.5 to 1.5 mL) for larger joints, depending on the specific disease entity being treated. Single injections into several joints, up to a total of 20 mg (2 mL) or more, have been given without incident.
- Intradermal: The initial dose of triamcinolone acetonide will vary depending upon the specific disease entity being treated but should be limited to 1 mg (0.1 mL) per injection site, since larger volumes are more likely to produce cutaneous atrophy.
- Multiple sites separated by 1 cm 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.
- Localization of Dose: The lower dosages in the initial dosage range of triamcinolone may produce the desired effect when the corticosteroid is administered to provide a localized concentration. The site and volume of the injection should be carefully considered when triamcinolone is administered for this purpose.
- General: The initial dosage should be maintained or adjusted until a satisfactory response is noted. If after a reasonable period of time there is a lack of satisfactory clinical response, KENALOG-10 should be gradually discontinued, and the patient transferred to other appropriate therapy.
- **Dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.** Dosage adjustments may be necessary in accordance with changes in clinical status.

4.4 Administration

Strict aseptic technique is mandatory. The vial should be shaken before use to ensure a uniform suspension. Prior to withdrawal, the suspension should be inspected for clumping or

granular appearance (agglomeration). Agglomeration occurs when the drug substance separates from the solution and appears as a white precipitate in the vial. An agglomerated product should be discarded and should not be used. After withdrawal, inject without delay to prevent settling in the syringe. Careful technique should be employed to avoid the possibility of entering a blood vessel or introducing infection.

Injection Technique: For treatment of joints, the usual intra-articular injection techniques should be followed. If an excessive amount of synovial fluid is present in the joint, some, but not all, should be aspirated to aid in the relief of pain and to prevent undue dilution of the steroid.

With intra-articular or intrabursal administration, and with injection of KENALOG-10 INJECTION into tendon sheaths or ganglia, prior use of a local anesthetic may often be desirable. Care should be taken with this kind of injection, particularly in the deltoid region, to avoid injecting the suspension into the tissues surrounding the site, since this may lead to tissue atrophy.

For treatment of ganglia, KENALOG-10 INJECTION is injected directly into the cyst cavity.

In treating acute nonspecific tenosynovitis, care should be taken to ensure that the injection of KENALOG-10 INJECTION is made into the tendon sheath rather than the tendon substance. Epicondylitis may be treated by infiltrating the preparation into the area of greatest tenderness.

Intralesional: For treatment of dermal lesions, KENALOG-10 INJECTION should be injected directly into the lesion, i.e., intradermally, or subcutaneously. For accuracy of dosage measurement and ease of administration, it is preferable to employ a tuberculin syringe and a small-bore needle (23 to 25 gauge). Ethyl chloride spray may be used to alleviate the discomfort of the injection.

5 OVERDOSAGE

Chronic

The symptoms of glucocorticoid overdose may include confusion, anxiety, depression, gastrointestinal cramping or bleeding, ecchymosis, moon face, and hypertension. After long-term use, rapid withdrawal can result in acute adrenal insufficiency (which may also occur in times of stress). Cushingoid changes can result from continued use of large doses.

Acute

There is no specific treatment for overdose, but supportive therapy should be instituted and, if gastrointestinal bleeding occurs, it should be treated as peptic ulcer.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
intra-articular and intradermal	Injectable Suspension 10 mg/mL	benzyl alcohol, carboxymethylcellulose sodium, hydrochloric acid, polysorbate, sodium chloride, sodium hydroxide, water

Each mL of sterile, aqueous suspension contains 10 mg of triamcinolone acetonide.

Description

KENALOG-10 (Triamcinolone Acetonide Injectable Suspension) is supplied as Vials of 5 mL. The pH is between 5.0 and 7.5. At the time of manufacture, the air in the container is replaced by nitrogen.

Medicinal ingredients: Each mL of sterile, aqueous suspension contains 10 mg of triamcinolone acetonide.

7 WARNINGS AND PRECAUTIONS

General

Because KENALOG-10 is a suspension, it should **not** be administered intravenously.

Epidural and intrathecal administration of this product should not be used. Reports of serious medical events have been associated with epidural and intrathecal routes of administration.

KENALOG-10 is a long-acting preparation and is **not** suitable for use in acute situations.

This product contains benzyl alcohol as a preservative. Benzyl alcohol has been associated with serious adverse events and death, particularly in pediatric patients. The "gasping syndrome" has been associated with benzyl alcohol. Although normal therapeutic doses of this product deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known. Premature and low-birth-weight infants, as well as patients receiving high dosages, may be more likely to develop toxicity.

Corticosteroids should be used with caution in the following conditions: Nonspecific ulcerative colitis (if there is a probability of perforation, abscess, or other pyogenic infection), diverticulitis, recent intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, acute glomerulonephritis, chronic nephritis, hypertension, congestive heart failure,

thrombophlebitis, thromboembolism, osteoporosis, exanthema, Cushing's syndrome, diabetes mellitus, convulsive disorders, metastatic carcinoma, myasthenia gravis.

Although therapy with KENALOG-10 may ameliorate symptoms of inflammation, it does not obviate the need to treat the cause.

In peptic ulcer, recurrence may be asymptomatic until perforation or hemorrhage occurs. Long-term adrenocortical therapy may itself produce hyperacidity or peptic ulcer. Therefore, anti-ulcer therapy is recommended.

Continued supervision of the patient after termination of triamcinolone acetonide therapy is essential since there may be a sudden reappearance of severe manifestations of the disease for which the patient was treated.

Patients should be advised to inform subsequent physicians of the prior use of corticosteroids.

Driving and Operating Machinery

The effects of corticosteroid therapy on the ability to drive or operate machinery have not been studied.

Endocrine and Metabolism

Average and large doses of hydrocortisone or cortisone 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, which may be associated with osteoporosis or aggravate pre-existing osteoporosis.

Drug induced adrenocortical insufficiency may occur with corticosteroids and persist for months after discontinuation of therapy; therefore, in any situation of stress such as trauma, surgery or severe illness occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

There is an enhanced corticosteroid effect in patients with hypothyroidism and in those with cirrhosis.

Like other potent corticosteroids, triamcinolone acetonide should be used under close clinical supervision. Triamcinolone acetonide can cause elevation of blood pressure, salt and water retention, and increased potassium and calcium excretion necessitating dietary salt restriction and potassium supplementation. Edema may occur in the presence of renal disease with a fixed or decreased glomerular filtration rate.

During prolonged therapy, **an adequate protein intake is essential** to counteract the tendency to gradual weight loss sometimes associated with negative nitrogen balance, wasting and weakness of skeletal muscles.

Genitourinary/Gynecologic

Menstrual irregularities may occur with corticosteroid treatment. In postmenopausal women, vaginal bleeding has been observed. Any unexpected bleeding or significant change in withdrawal bleeding should prompt further investigation.

Immune

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. In addition, patients who are on immunosuppressant drugs including corticosteroids are more susceptible to infections than those not taking these drugs. Moreover, chickenpox and measles can have a more serious or even fatal course in patients on corticosteroids. In such children, or adults receiving corticosteroids who have not had these diseases, particular care should be taken to avoid exposure. If exposed, therapy with varicella zoster immune globulin (VZIG) or pooled intravenous immunoglobulin (IVIG), as appropriate, may be indicated. If chickenpox or herpes zoster develops, treatment with antiviral agents may be considered. Similarly, corticosteroids should be used with great caution in patients with Strongyloides (threadworm) infestation because corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal Gram-negative septicemia.

Patients should not be vaccinated or immunized while on corticosteroid therapy, especially on high doses, because of a lack of antibody response predisposing to medical complications, particularly neurological ones.

Hepatitis B virus reactivation can occur in patients who are hepatitis B carriers treated with immunosuppressive dosages of corticosteroids, including KENALOG-10 INJECTION. Reactivation can also occur infrequently in corticosteroid-treated patients who appear to have resolved hepatitis B infection. Screen patients for hepatitis B infection before initiating immunosuppressive treatment with KENALOG-10 INJECTION.

For patients who show evidence of current or previous hepatitis B infection, recommend consultation with physicians with expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.

The use of triamcinolone acetonide in patients with active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen. Chemoprophylaxis should be used in patients with latent tuberculosis or tuberculin reactivity who are taking corticosteroids.

Musculoskeletal

Intra-articular injection of a corticosteroid may produce systemic as well as local effects. The inadvertent injection of the suspension into the soft tissues surrounding a joint may lead to the occurrence of systemic effects and is the most common cause of failure to achieve the desired local results. Following intra-articular steroid therapy, patients should be specifically warned to avoid overuse of joints in which symptomatic benefit has been obtained. Otherwise, an increase in joint deterioration can occur.

Over distention of the joint capsule and deposition of steroid along the needle track should be avoided in intra-articular injection since this may lead to subcutaneous atrophy.

Corticosteroids should not be injected into unstable joints. Repeated intra-articular injection may in some cases itself result in instability of the joint. In selected cases, particularly where repeated injections are given, x-ray follow-up is suggested.

An increase in joint discomfort has seldom occurred. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of a septic arthritis. If these complications should appear, and the diagnosis of septic arthritis is confirmed, administration of triamcinolone acetonide should be stopped, and antimicrobial therapy should be instituted immediately and continued for 7 to 10 days after all evidence of infection has disappeared. Appropriate examination of any joint fluid present is necessary to exclude a septic process. Injection of a steroid into a previously infected joint should therefore be avoided. Repeated injection into inflamed tendons has been followed by tendon rupture. Therefore, it should also be avoided.

Psychiatric

Psychiatric disturbances may appear when corticosteroids are used. These can include insomnia, depression (sometimes severe), euphoria, mood swings, psychotic symptoms, and personality changes. Pre-existing emotional instability or psychosis may also be aggravated by corticosteroids. The use of antidepressant drugs does not relieve and may exacerbate adrenocorticoid-induced mental disturbances.

Ophthalmologic

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroid including triamcinolone acetonide.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts or glaucoma with possible damage to the optic nerve. Prolonged use may also enhance the likelihood of secondary ocular infections.

Adequate studies to demonstrate the safety of KENALOG-10 INJECTION use by intraturbinal, subconjunctival, sub-tenons, retrobulbar and intraocular (intravitreal) injections have not been performed.

Endophthalmitis, eye inflammation, increased intraocular pressure, chorioretinopathy, including crystalline maculopathy and viral retinitis (mainly by cytomegalovirus) and visual disturbances including vision loss have been reported with intravitreal administration. Several instances of blindness have been reported following injection of corticosteroid suspensions into the nasal turbinates and intralesional injection about the head. Administration of KENALOG-10 INJECTION by intraturbinal, subconjunctival, sub-tenons, retrobulbar and intraocular (intravitreal) injections is not recommended.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

Sensitivity / Resistance

Cases of serious anaphylactic reactions and anaphylactic shock, including death, have been reported in individuals receiving triamcinolone acetonide injection, regardless of the route of administration.

Rare instances of anaphylactoid reactions have occurred in patients receiving parenteral corticosteroid therapy. Appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of allergy to any drug.

7.1 Special Populations

7.1.1 Pregnant Women

Many corticosteroids have been shown to be teratogenic in laboratory animals at low doses. Since adequate human reproduction studies have not been performed with corticosteroids, the use of these drugs in pregnancy, nursing mothers, or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and the embryo, fetus, or breast-fed infant. Other systemic corticosteroids have been shown to appear in breast milk and to slightly elevate (by 1%) the risk of cleft palate in human fetuses. Infants born to mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of adrenal suppression.

7.1.2 Breast-feeding

Many corticosteroids have been shown to be teratogenic in laboratory animals at low doses. Since adequate human reproduction studies have not been performed with corticosteroids, the use of these drugs in pregnancy, nursing mothers, or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and the embryo, fetus, or breast-fed infant. Other systemic corticosteroids have been shown to appear in breast milk and to slightly elevate (by 1%) the risk of cleft palate in human fetuses. Infants born to mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of adrenal suppression.

7.1.3 Pediatrics

KENALOG-10 INJECTION is not for use in newborn or preterm infants.

Because corticosteroids can suppress growth, the development of infants and children on prolonged corticosteroid therapy should be carefully observed. Caution should be used in the event of exposure to chickenpox, measles, or other communicable diseases. Children should not be vaccinated or immunized while on corticosteroid therapy. (See 7 WARNINGS AND PRECAUTIONS, Immune).

Corticosteroids may also affect endogenous steroid production.

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.

7.1.4 Geriatrics

The common adverse effects of systemic corticosteroids such as osteoporosis or hypertension may be associated with more serious consequences in old age. Close clinical supervision is recommended.

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Undesirable reactions following intra-articular administration of the preparation have included post-injection flare, transient pain, irritation at the injection site, sterile abscesses, hyper- or hypopigmentation, Charcot-like arthropathy, and occasional increase in joint discomfort. Following intradermal administration, rare instances of blindness associated with intralesional therapy around the face and head, transient local discomfort, sterile abscesses, hyper- or hypopigmentation, cutaneous and subcutaneous atrophy (which usually disappears, unless the basic disease process is itself atrophic) have occurred.

Since systemic absorption may occasionally occur with intra-articular or other local administration, patients should be watched closely for the following adverse reactions which may be associated with any corticosteroid therapy:

General: anaphylactoid reactions, anaphylactic reactions, anaphylactic shock, aggravation, or masking of infections.

Cardiovascular: hypertension, syncope, congestive heart failure, arrhythmias, necrotizing angiitis, thromboembolism, thrombophlebitis.

Fluid and Electrolyte Disturbances: sodium retention, fluid retention associated with hypertension or congestive heart failure, potassium loss which may lead to cardiac arrhythmias or ECG changes, hypokalemic alkalosis.

Musculoskeletal: muscle weakness, fatigue, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, delayed healing of fractures, aseptic necrosis of femoral and humeral heads, pathologic fractures of long bones, spontaneous fractures.

Gastrointestinal: peptic ulcer with possible subsequent perforation and hemorrhage, pancreatitis, abdominal distention, ulcerative esophagitis.

Dermatologic: impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, purpura, striae, hirsutism, acneiform eruptions, lupus erythematosus-like lesions, hives, rash, suppressed reactions to skin tests.

Neuropsychiatric: convulsions, increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment, vertigo, headache, insomnia, neuritis, parasthesias,

aggravation of pre-existing psychiatric conditions, depression (sometimes severe), euphoria, mood swings, psychotic symptoms, personality changes.

Endocrine: menstrual irregularities, postmenopausal vaginal haemorrhage, development of the cushingoid state, suppression of growth in children, secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g., trauma, surgery, or illness), decreased carbohydrate tolerance, manifestations of latent diabetes mellitus, increased requirements for insulin or oral hypoglycemic agents in diabetics.

Ophthalmic: central serous chorioretinopathy, posterior subcapsular cataracts, increased intra-ocular pressure, glaucoma, exophthalmos, corneal perforation, blurred vision.

Metabolic: hyperglycemia, glycosuria, negative nitrogen balance due to protein catabolism.

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

Amphotericin B injection and potassium-depleting agents: Patients should be observed for hypokalemia.

Anticholinesterases: Effects of the anticholinesterase agent may be antagonized.

Anticoagulants, oral: Corticosteroids may potentiate or decrease anticoagulant action. Patients receiving oral anticoagulants and corticosteroids should therefore be closely monitored.

Antidiabetics: Corticosteroids may increase blood glucose; diabetic control should be monitored, especially when corticosteroids are initiated, discontinued, or changed in dosage.

Antitubercular drugs: Isoniazid serum concentrations may be decreased.

Cyclosporine: Monitor for evidence of increased toxicity of cyclosporine when the two are used concurrently.

CYP 3A4 inhibitors: Triamcinolone acetonide is a substrate of CYP3A4. Caution is advised in co-administration of strong CYP3A4 inhibitors (e.g., grapefruit or its juice, ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, telithromycin) with KENALOG-10 INJECTION, because increased systemic corticosteroid adverse effects may occur (see 8 ADVERSE REACTIONS). During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving triamcinolone acetonide and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression (see 5 OVERDOSAGE and 7 WARNINGS AND PRECAUTIONS, General).

Digitalis glycosides: Co-administration may enhance the possibility of digitalis toxicity.

Estrogens, including oral contraceptives: Corticosteroid half-life and concentration may be increased, and clearance decreased.

Hepatic enzyme inducers (e.g., barbiturates, phenytoin, carbamazepine, rifampin): There may be increased metabolic clearance of KENALOG-10 INJECTION. Patients should be carefully observed for possible diminished effect of steroid, and the dosage of KENALOG-10 INJECTION should be adjusted accordingly.

Human growth hormone (e.g., somatrem): The growth-promotion effect of somatrem may be inhibited.

Nondepolarizing muscle relaxants: Corticosteroids may decrease or enhance the neuromuscular blocking action.Nonsteroidal anti-inflammatory agents (NSAIDS): Corticosteroids may increase the incidence and/or severity of gastrointestinal bleeding and ulceration associated with NSAIDS. Also, corticosteroids can reduce serum salicylate levels and therefore decrease their effectiveness. Conversely, discontinuing corticosteroids during high-dose salicylate therapy may result in salicylate toxicity. Acetylsalicylic acid should be used cautiously in conjunction with corticosteroids in patients with hypoprothrombinemia.

Thyroid drugs: Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in adrenocorticoid dosage.

Vaccines: Neurological complications and lack of antibody response may occur when patients taking corticosteroids are vaccinated (see 7 WARNINGS AND PRECAUTIONS, Immune).

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Corticosteroids may affect the nitroblue tetrazolium test for bacterial infection, producing false negative results.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

Naturally occurring glucocorticoids (e.g., hydrocortisone), 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 potent anti-inflammatory effects in disorders of many organ systems.

Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

11 STORAGE, STABILITY AND DISPOSAL

Store at controlled room temperature (15°C to 30°C). Do not freeze or refrigerate. Protect from light.

Once in use: Use within 28 days of first puncture when stored at 15°C to 25°C.

12 SPECIAL HANDLING INSTRUCTIONS

Due to the high potency of this drug and its potential for absorption through the skin, persons who handle KENALOG-10 INJECTION should avoid skin and eye contact, as well as inhalation of airborne drug.

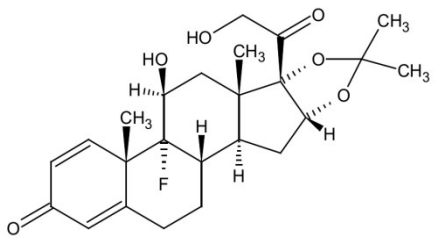
PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:	Triamcinolone Acetonide
Chemical name:	9-Fluoro-11β,16α,17,21-tetrahydroxypregna1,4-diene-3,20-dione cyclic 16,17-acetal with acetone
Molecular formula and molecular mass:	$C_{24}H_{31}FO_6$, 434.51 g/mol

Structural formula:



Product Characteristics:

KENALOG-10 INJECTION is triamcinolone acetonide, a synthetic glucocorticoid corticosteroid with marked anti-inflammatory action, in a sterile aqueous suspension.

14 CLINICAL TRIALS

Not applicable.

15 MICROBIOLOGY

Not applicable.

16 NON-CLINICAL TOXICOLOGY

Not applicable.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrKENALOG®-10 INJECTION

triamcinolone acetonide injection

Read this carefully before you start taking **KENALOG-10 INJECTION** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **KENALOG-10 INJECTION.**

What is KENALOG-10 INJECTION used for?

KENALOG-10 INJECTION is used to treat a variety of conditions such as types of arthritis, allergic diseases and skin diseases.

How does KENALOG-10 INJECTION work?

KENALOG-10 INJECTION contains triamcinolone acetonide, which is a corticosteroid hormone. It works by decreasing your body's immune response to certain diseases and reduces symptoms such as swelling.

What are the ingredients in KENALOG-10 INJECTION?

Medicinal ingredient: triamcinolone acetonide

Non-medicinal ingredients: benzyl alcohol, carboxymethylcellulose sodium, hydrochloric acid, polysorbate, sodium chloride, sodium hydroxide, water.

KENALOG-10 INJECTION comes in the following dosage forms:

Suspension for injection, 10 mg / mL.

Do not use KENALOG-10 INJECTION if:

- you are allergic to triamcinolone acetonide or any of the other ingredients of this medication (see **What are the ingredients in KENALOG-10 INJECTION?**)
- you have an infection in your blood (a systemic infection)
- you have an infection in the area KENALOG-10 INJECTION is to be injected

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KENALOG-10 INJECTION. Talk about any health conditions or problems you may have, including if you:

- have blood clots, or an infection or inflammation of the veins in your legs
- have osteoporosis (thin or brittle bones; bone loss)
- have a history of any form of cancer, especially metastatic cancer that has spread within the body

- have Cushing's syndrome (a disease that occurs when your body makes too much of the hormone cortisol, or the body's "stress hormone")
- have certain eye diseases (such as cataracts, glaucoma (increased pressure in your eyes), herpes infection of the eye), or experienced blurred vision or other visual disturbance, loss of vision, eye inflammation and viral retinitis mainly caused by cytomegalovirus
- have or have a history of heart problems (such as heart failure)
- have high blood pressure
- have diabetes
- have a current infection or have had one in the past (such as joint infections and infections caused by fungus, herpes, tuberculosis, threadworm)
- have kidney or liver problems. Your healthcare professional may need to adjust your dose of KENALOG-10 INJECTION.
- have or have a history of mental health problems (such as psychosis, anxiety, depression)
- have a neuromuscular disease called myasthenia gravis (a condition which causes weak muscles)
- have stomach or intestinal problems (such as diverticulitis, active or latent peptic ulcer, ulcerative colitis, recent bowel surgery, especially if there is a chance of perforation, abscess, or other infection)
- have or have a history of seizures or epilepsy
- have a disease called exanthema that causes a serious skin rash
- have a history of thyroid problems. Your healthcare professional may need to adjust your dose of KENALOG-10 INJECTION.
- have a mineral imbalance (such as low levels of potassium or calcium in your blood)
- are pregnant or plan to become pregnant
- are breastfeeding
- are 65 years of age or older. You may be more at risk of side effects.

Other warnings you should know about:

Diabetes and high blood sugar

- This medication may make your blood sugar rise, which can cause or worsen diabetes. Tell your healthcare professional right away if you have symptoms of high blood sugar such as increased thirst/urination. If you already have diabetes, check your blood sugar regularly as directed and share the results with your healthcare professional.

Immune system

- Taking medicines like KENALOG-10 INJECTION can affect how your immune system responds to stress such as trauma, surgery or severe illness. This can continue even after you have stopped treatment. You should tell any healthcare professional you see that you have been treated with KENALOG-10 INJECTION.
- KENALOG-10 INJECTION can mask signs of new infections and make you more susceptible to infections.
- You should avoid contact with people who have chickenpox, shingles or measles, especially if you have never had them. An infection with any of these could affect you severely. If you do come into contact with chickenpox, shingles or measles, talk to your healthcare professional right away.

Children and infants

- Corticosteroids can suppress or stunt growth. Therefore, growth and development of children should be carefully observed by during long term treatment with KENALOG-10 INJECTION.
- KENALOG-10 INJECTION contains benzyl alcohol and must not be given to premature or newborn babies.

Allergic reactions

- Serious allergic reactions and anaphylactic shock, including death, have been reported in patients being treated with KENALOG-10 INJECTION. See the **Serious side effects and what to do about them** table, below, for more information and this and other serious side effects.

If you are due to have surgery

- Before surgery and anaesthesia (even at the dentist) you should tell your healthcare professional that you are being treated with KENALOG-10 INJECTION.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with KENALOG-10 INJECTION:

- vaccines: if you have had any recent vaccinations, need to have a vaccine or are not sure, talk to your healthcare professional
- medicines used to treat thyroid problems. Your healthcare professional may need to adjust your dose of KENALOG-10 INJECTION.
- muscle relaxants
- human growth hormone
- estrogens, including oral birth control pills
- cyclosporine, a medicine used to suppress the immune system after organ transplant
- medicines for diabetes
- medicines used to treat fungal infections, such as amphotericin B, itraconazole, ketoconazole
- potassium depleting medications, such as diuretics or “water pills”, used to treat high blood pressure
- anticholinesterases, used to treat high cholesterol
- medications used to treat tuberculosis (TB)
- medicines used to treat HIV infection and AIDS, such as ritonavir, atazanavir, indinavir, nelfinavir, saquinavir
- antibiotic medicines used to treat bacterial infections, such as clarithromycin, telithromycin
- nefazodone, an anti-depressant
- medicines that may cause an irregular heartbeat such as digitalis glycosides, used to treat heart problems
- medicines used to treat seizures, such as barbiturates, phenytoin, carbamazepine, rifampin. Your healthcare professional may need to adjust your dose of KENALOG-10 INJECTION.
- medicines used to thin the blood and prevent blood clots, such as clopidogrel, NSAIDs (such as ibuprofen, naproxen), aspirin, warfarin, dabigatran

Blood tests: KENALOG-10 INJECTION may interfere with some blood tests including the nitroblue tetrazolium test for bacterial infection. If you need to have blood tests, tell your healthcare professional that you are being treated with KENALOG-10 INJECTION.

How to take KENALOG-10 INJECTION:

- KENALOG-10 INJECTION will be given to you by a trained healthcare professional in a clinical setting.
- It will be given by injecting it into different locations such as under the skin (intradermal) or into a joint (intra-articular). You may receive one or more injections depending on the condition being treated.

Usual dose:

Your healthcare professional will decide on the dose that is right for you depending on the condition being treated.

Overdose:

If you think you, or a person you are caring for, have been given too much KENALOG-10 INJECTION, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using KENALOG-10 INJECTION?

These are not all the possible side effects you may have when taking KENALOG-10 INJECTION. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- pain and irritation at the injection site
- joint pain
- fatigue
- rash
- changes in skin pigmentation (darker or lighter)
- increased sweating
- acne
- bloating
- dizziness (vertigo)
- headache
- trouble sleeping (insomnia)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Edema: unusual swelling of the arms, hands, legs, feet or ankles	X		
Mental health problems: behavioral changes, depression, mood swings	X		
Skin and subcutaneous atrophy: wasting away of body tissue in the area of the injection, red spots, swelling, redness, itching or burning	X		
UNCOMMON			
Aggravation or masking of infection: worsening of an infection or hiding the signs and symptoms of some infections, fever, body aches, chills, sore throat or other signs of infection	X		
Menstrual irregularities: irregular periods, postmenopausal women may experience vaginal bleeding	X		
Myopathy: muscular weakness and discomfort, loss of muscle mass	X		
Osteoporosis (thin fragile bones): broken bones, pain, back pain that gets worse when standing or walking		X	
Peptic ulcer (with possible perforation and hemorrhage): heartburn, long lasting stomach pain, loss of appetite and weight loss, vomiting blood, blood in stool, dark or tarry stool		X	
Skin problems: small purple spots, large spots or solid redness, skin irritation and itching, impaired wound healing, thin fragile skin, stretch marks	X		
RARE			

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Allergic reaction: swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, rash or hives, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up			X
Convulsions: seizure, spasms, shaking or fits			X
Electrolyte imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat	X		
Eye disorders: visual disturbance, blurred vision, loss of vision, increased sensitivity to light, eye pain, redness or irritation, seeing halos around lights		X	
Heart problems: fainting, irregular heartbeat, palpitations, shortness of breath, chest pain		X	
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision, fatigue		X	
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations		X	
Hypokalemia (low levels of potassium in the blood): muscle weakness, muscle spasms, cramping, constipation, heart palpitations, fatigue, tingling or numbness	X		
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heartbeat, nausea, vomiting, tenderness when touching the abdomen		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Thromboembolism (blood clot in a vein or artery): pain, tenderness or swelling in your arm or leg, skin that is red or warm, coldness, tingling or numbness, pale skin, muscle pain or spasms, weakness			X
Thrombophlebitis: swelling and redness along a vein which is extremely tender or painful when touched		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store KENALOG-10 INJECTION at 15˚C – 30˚C. Do not freeze or refrigerate. Protect from light.

Once in use: Use within 28 days of first puncture when stored at 15°C to 25°C.

Keep out of reach and sight of children.

If you want more information about KENALOG-10 INJECTION:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-

product-database.html; the manufacturer's website: https://www.bms.com/ca, or by calling 1-866-463-6267.

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