Product Monograph

Including Patient Medication Information

PrKENALOG®-40 INJECTION

triamcinolone acetonide injection

Injectable Suspension, 40 mg/mL, Intra-Articular, Intramuscular

USP

Corticosteroid

Bristol-Myers Squibb Canada

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Date of Preparation:
DEC 31, 1973

Date of Revision:

JAN 08, 2025

Submission Control Number: 289140

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-40 INJECTION (triamcinolone acetonide) is indicated for:

- Intramuscular (I.M.): The I.M. administration is indicated for systemic corticosteroid therapy in such conditions as dermatoses or generalized rheumatoid arthritis and other connective tissue disorders. It is also indicated for allergic diseases; however, for acute allergic reactions, epinephrine is the drug of choice, steroid therapy being adjunctive.

  I.M. administration is particularly valuable in such conditions when oral corticosteroid therapy is not feasible. Triamcinolone acetonide is not an agent of choice in the treatment of adrenocortical insufficiency or the salt-losing form of the adrenogenital syndrome.

- 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.

1.1 Pediatrics

Pediatrics (<18 years of age): KENALOG-40 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

- I.M. corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura.

- KENALOG-40 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 contraindicated in patients with systemic infections. 4

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

- NOTE: KENALOG-40 INJECTION is a synthetic glucocorticoid corticosteroid with marked anti-inflammatory action, in a sterile aqueous suspension suitable for intramuscular, intra-articular, and intrabursal injection. **This formulation is not suitable for intravenous, intradermal, intraocular, epidural or intrathecal injection.**

- This preparation contains benzyl alcohol. KENALOG-40 INJECTION is not for use in newborn or premature infants, (see 7.1.3 WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics).

- The initial dose of KENALOG-40 INJECTION may vary from 2.5 to 60 mg/day depending on the specific disease entity being treated. In less severe conditions, lower doses generally suffice, while in other patients, higher initial doses may be required. Usually the parenteral dosage range is one-third to one-half the oral dose, given every 12 hours. In life-threatening situations, administration of higher dosages may be justified.

- 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-40 INJECTION 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.** The lowest possible dose of corticosteroid should be used to control the condition being treated. 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 down to the lowest dosage which will maintain the desired clinical response. Constant monitoring of drug dosage is necessary. Dose adjustments may be necessary in accordance with changes in clinical status. Patient exposure to stressful situations not directly related to the disease may necessitate increasing the dosage. After long-term therapy, it is recommended that KENALOG-40 INJECTION be withdrawn gradually.

4.2 Recommended Dose and Dosage Adjustment

- **Systemic Dose:**

- Adults and children over 12 years of age: The suggested initial dose is 60 mg (1.5 mL), injected deeply into the gluteal muscle. Atrophy of subcutaneous fat may occur if the injection is not properly given. Dosage is usually adjusted within the range of 40 to 80 mg, depending upon patient response and duration of relief. However, some patients may be well controlled on doses as low as 20 mg or less.
- Hay fever or pollen asthma: Patients with hay fever or pollen asthma who are not responding to pollen administration and other conventional therapy may obtain a remission of symptoms lasting throughout the pollen season after a single injection of 40 to 100 mg (1 to 2.5 mL).
- Children 6 to 12 years: The suggested initial dose is 40 mg (1 mL), although dosage depends more on the severity of symptoms than on age or weight. There is insufficient clinical experience with KENALOG-40 INJECTION to recommend its use in children under 6 years of age.

- **Local Dose**:
  - Intra-articular or intrabursal administration and for injection into tendon sheaths: A single local injection of triamcinolone acetonide is frequently sufficient, but several injections may be needed for adequate relief of symptoms.
  - Initial Dose: 2.5 to 5 mg (0.063 to 0.125 mL) for smaller joints and from 5 to 15 mg (0.125 to 0.375 mL) for larger joints, depending on the specific disease entity being treated. For adults, doses up to 10 mg (0.25 mL) for smaller areas and up to 40 mg (1 mL) for larger areas have usually been sufficient. Single injections into several joints, up to a total of 80 mg (2 mL), have been given without undue reactions.

4.4 Administration

- General: **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, KENALOG-40 INJECTION should be injected 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.
- Systemic: For systemic therapy, injection should be made **deeply into the gluteal muscle** (see 7 WARNINGS AND PRECAUTIONS, General). For adults, a minimum needle length of 4 cm is recommended. In obese patients, a longer needle may be required. Use alternative sites for subsequent injections.

- Local: For treatment of joints, 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 into tendon sheaths, prior use of a local anesthetic may often be desirable. Care should be taken with this kind of injection, particularly in the deltoid region, and with injection into tendon sheaths to avoid injecting the suspension into the tissues surrounding the site, since this may lead to tissue atrophy.
- In treating acute nonspecific tenosynovitis, care should be taken to ensure that the injection of the corticosteroid 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.

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 acute overdose, but supportive therapy should be instituted and, if gastrointestinal bleeding occurs, it should be managed.

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, intramuscular	Injectable Suspension 40 mg/mL	benzyl alcohol, carboxymethylcellulose sodium, hydrochloric acid, polysorbate, sodium chloride, sodium hydroxide, water

Each mL of sterile, aqueous suspension contains 40 mg of triamcinolone acetonide.

Availability: KENALOG-40 INJECTION (Triamcinolone Acetonide Injectable Suspension) is supplied as Vials of 1 and 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.

7 WARNINGS AND PRECAUTIONS

General

Because KENALOG-40 INJECTION is a suspension, it should **not** be administered intravenously. The subcutaneous route of administration must not be used, due to the possibility of local atrophy.

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.

Adequate studies to demonstrate the safety of KENALOG-40 INJECTION use by intraturbinal, subconjunctival, sub-tenons, retrobulbar and intraocular (intravitreal) injections have not been performed. Endophthalmitis, eye inflammation, increased intraocular pressure 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-40 INJECTION by any of these routes is not recommended.

KENALOG-40 INJECTION is a long-acting preparation and is not suitable for use in acute situations. To avoid drug-induced adrenal insufficiency, supportive dosage may be required in times of stress (such as trauma, surgery or severe illness) both during treatment with KENALOG-40 INJECTION and for a year afterwards.

Unless a **deep** I.M. injection is given, local atrophy is likely to occur. For recommendations on injection techniques (see 4.3 DOSAGE AND ADMINISTRATION, Administration). Due to the significantly higher incidence of local atrophy when the material is injected into the deltoid area, this injection site should be avoided in favor of the gluteal area.

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-40 INJECTION 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, antiulcer therapy is recommended.

Continued supervision of the patient after termination of triamcinolone 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 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 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.

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 also 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.

Overdistention 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-40 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-40 INJECTION by any of these routes 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 child-bearing 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 child-bearing 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

Children: KENALOG-40 INJECTION is not for use in newborn or preterm infants. This preparation is not recommended for children under 6 years of age. Because corticosteroids can suppress growth, the development of 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

General: Following administration by any route, 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, 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, blurred vision, corneal perforation.

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

Following I.M. administration: Severe pain has been reported following I.M. administration. Sterile abscesses, cutaneous and subcutaneous atrophy, hyperpigmentation, hypopigmentation, and Charcot-like arthropathy have also occurred.

Intra-articular administration: Undesirable reactions have included post-injection flare, transient irritation at the injection site, sterile abscesses, cutaneous and subcutaneous atrophy, hyper-or hypopigmentation, Charcot-like arthropathy, and occasional increase in joint discomfort (see 7 WARNINGS AND PRECAUTIONS, Musculoskeletal).

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: Increased activity of both cyclosporine and corticosteroids may occur 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-40, because increased systemic corticosteroid adverse effects may occur (see 7 ADVERSE REACTIONS, Endocrine). 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 7 WARNINGS AND PRECAUTIONS, Endocrine and Metabolism, and 5 OVERDOSAGE).

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-40 INJECTION. Patients should be carefully observed for possible diminished effect of steroid, and the dosage of KENALOG-40 INJECTION should be adjusted accordingly.

Human growth hormone (e.g., somatrem): The growth-promoting 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

10.2 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 analogues 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.

KENALOG-40 INJECTION has an extended duration of effect which may be permanent or sustained over a period of several weeks. Studies indicate that following a single I.M. dose of 60 to 100 mg of triamcinolone acetonide, adrenal suppression occurs within 24 to 48 hours and then gradually returns to normal, usually in 30 to 40 days. This finding correlates closely with the extended duration of therapeutic action achieved with the drug.

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-40 INJECTION should avoid skin and eye contact, as well as inhalation of airborne drug.

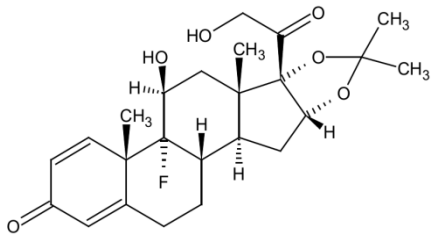
PART II: SCIENTIFIC INFORMATION

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-40 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-40 INJECTION

triamcinolone acetonide injection

Read this carefully before you start taking **KENALOG-40 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-40 INJECTION.**

What is KENALOG-40 INJECTION used for?

KENALOG-40 INJECTION is used to treat a variety of conditions such as types of arthritis, allergic diseases and skin diseases.

How does KENALOG-40 INJECTION work?

KENALOG-40 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-40 INJECTION?

Medicinal ingredient: triamcinolone acetonide

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

KENALOG-40 INJECTION comes in the following dosage forms:

Suspension for injection, 40 mg / mL.

Do not use KENALOG-40 INJECTION if:

- you are allergic to triamcinolone acetonide or any of the other ingredients of this medication (see **What are the ingredients in KENALOG-40 INJECTION?**)
- you have an infection in your blood (a systemic infection)
- you have an immune disorder called idiopathic thrombocytopenic purpura which can cause an increased risk of bleeding

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KENALOG-40 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-40 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-40 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-40 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-40 INJECTION.
- KENALOG-40 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

- KENALOG-40 INJECTION is not recommended in children under 6 years. It may be given to older children in suitably adjusted dosages.
- Corticosteroids can suppress or stunt growth. Therefore, growth and development of children should be carefully observed by during long term treatment with KENALOG-40 INJECTION.
- KENALOG-40 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-40 INJECTION. See the **Serious side effects and what to do about them** table, below, for more information on 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-40 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-40 INJECTION:

- vaccines: if you have had any recent vaccinations, need to have a vaccine or are not sure, please talk to your healthcare professional
- medicines used to treat thyroid problems. Your healthcare professional may need to adjust dose of KENALOG-40 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 injection and AIDS, sch 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-40 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-40 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-40 INJECTION.

How to take KENALOG-40 INJECTION:

- KENALOG-40 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 a muscle (intramuscularly) or a joint (intra-articularly). 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-40 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-40 INJECTION?

These are not all the possible side effects you may have when taking KENALOG-40 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-40 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-40 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.

This leaflet was prepared by Bristol-Myers Squibb Canada.

Last Revised: JAN 08, 2025