

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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