

PATIENT INFORMATION LEAFLET
KENALOG™
INTRA-ARTICULAR / INTRAMUSCULAR INJECTION 40 mg/ml
Triamcinolone Acetonide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

- **Kenalog IA/IM Injection is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Kenalog IA/IM Injection can cause side effects in some people** (read section 4 below). Some problems such as mood changes (feeling depressed or 'high'), or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets, **but see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a rounder face (read section 4 for more information).
- **If you take it for more than 3 weeks, you will get a blue 'Steroid Treatment Card'; if your doctor administers Kenalog IA/IM Injection for a longer period, and you have to return for a new dose a number of times, you should also carry a 'Steroid Emergency Card'**: always keep these cards with you and show them to any doctor or nurse treating you.
- **Keep away from people who have chicken pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away**.

What is in this leaflet

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2. What you need to know before you are given Kenalog IA/IM Injection
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1. What Kenalog IA/IM Injection is and what it is used for

The name of this medicine is Kenalog IA/IM Injection. Each injection contains triamcinolone acetonide 40 mg/ml as the active ingredient. Triamcinolone acetonide belongs to a group of medicine called corticosteroids (steroids).

Kenalog IA/IM Injection is for the treatment of joint pain, swelling and stiffness in inflammatory disorders such as rheumatoid arthritis.

It is also for the treatment of various allergic disorders including asthma, blood disorders, hormone problems, rheumatic fever, and problems associated with digestive system, kidneys, lungs or skin.

2. What you need to know before you are given Kenalog IA/IM Injection

Do not receive Kenalog IA/IM Injection if;

- You have had an allergic reaction to a similar medicine or any of the ingredients in this medicine. See section 6 for full list of ingredients
- You are suffering from an infection unless your doctor has also prescribed a treatment for the infection.

Kenalog IA/IM Injection is not recommended for children under 6 years.

You must tell your doctor if:

- You have had any recent infection [including tuberculosis (TB)]
- You have had recent bowel surgery
- You have, or have had a bowel disorder or stomach ulcer
- You have an infection or inflammation of the veins in your legs
- You have had any mental health disorders or epilepsy
- You have had any kidney, liver or thyroid (gland in the neck) problems as the dose of Kenalog may need to be adjusted
- You have recently suffered from any form of cancer
- You have thin or brittle bones (osteoporosis)
- You have myasthenia gravis (a disease which causes weak muscles)
- You have high blood pressure or heart failure
- You or someone in your family has glaucoma (increased pressure in your eyes)
- you have visual disturbances, loss of vision, eye inflammation (red, bloodshot aching eye) and viral retinitis (inflammation of retina caused mainly by cytomegalovirus). Inflammation of the retina can affect your vision if not treated. Symptoms of inflammation includes experiencing loss of vision, general blurriness of vision, blind spots, seeing flashes of light or floaters (dark spots and squiggles in vision).
- You are diabetic as your insulin dose may need to be changed

Contact your doctor if you experience blurred vision or other visual disturbances.

Check with your doctor first:

- If you are taking triamcinolone acetonide [Kenalog IA/IM Injection] and medicines to control HIV (anti-retrovirals) or fungal infections (anti-fungals) because you could experience more adverse effects and your doctor may wish to monitor you carefully. Refer to list of medicines mentioned in “Taking other medicines with Adcortyl IA/ID Injection.”
- **If you have ever had severe depression** or manic-depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Kenalog IA/IM Injection.

- If any of your close family has had these illnesses.

If any of these applies to you, **talk to a doctor before taking Kenalog IA/IM Injection.**

Steroid medicines suppress your body's natural immune response. Therefore, if you come into contact with anyone who has an infectious disease such as chickenpox, shingles or measles, consult your doctor as soon as possible.

While you are being treated with this medicine (or if you have recently stopped a course of treatment) do not have any vaccination without consulting your doctor.

You must take care not to over-use a joint which feels better after you receive Kenalog IA/IM injection. The joint will still need to recover from the inflammation which caused your symptoms.

Taking other medicines with Kenalog IA/IM Injection

Please tell your doctor if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Adcortyl and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

This is especially important if you are taking;

- Aspirin, ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs) as corticosteroids can increase the chance of bleeding from the gut.
- Anti-retroviral inhibitors and anti-fungals: ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, and telithromycin because increased adverse effects may occur, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression
- Warfarin or other medicines to thin the blood
- Oral contraceptive pill or hormone replacement therapy (HRT)
- Human growth hormone
- A medicine called ciclosporin
- A medicine called rifampicin

or medicines to treat;

- High blood pressure or irregular heart beat (e.g. digoxin)
- Myasthenia gravis (a disease which causes weak muscles)
- Epilepsy or other sorts of fits (e.g. phenytoin)
- Tuberculosis (TB)
- Diabetes
- Thyroid problems

If you are taking any of these medicines, or are not sure, please consult your doctor.

If you are due to have surgery

Before surgery and anaesthesia (even at the dentist) you should tell the doctor or dentist that you are being treated with Kenalog IA/IM injection.

Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant, or if you are breast-feeding you should make sure you discuss this with your doctor as soon as possible before receiving Kenalog IA/IM injection.

Driving and using machines

This medicine does not usually affect your ability to drive or operate machinery but it can affect your eyesight. Tell your doctor immediately if you have any pain in the eyes, problems with your vision.

Steroid Treatment Card and Steroid Emergency Card

Your doctor or pharmacist will have given you a '**Steroid Treatment Card**' and, if required also a '**Steroid Emergency Card**' with your prescription or medicine.

YOU SHOULD ALWAYS CARRY THESE CARDS WITH YOU as they must be shown to any of the following persons:

Doctor or Nurse - before having any surgery or emergency treatment or if any new treatment is prescribed.

Dentist - before having any dental surgery

Pharmacist - before buying any medicine

Optician - it is advisable to have regular eye tests

Important information about the ingredients of Kenalog IA/IM Injection

Kenalog IA/IM Injection contains 15 mg/ml benzyl alcohol which may cause harmful or allergic reactions in infants and children. Kenalog IA/IM injection must not be given to premature or newly born babies

3. Receiving Kenalog IA/IM Injection

The effect of the injection will vary from patient to patient and further injections may be given to you when symptoms return and not at regular intervals.

The usual doses are;

Use in inflammatory joint disorders:

The dose of injection into a joint or tendon sheath depends upon the size of the joint to be treated and the severity of the condition which is being treated. Doses of 5-10 mg (0.125-0.25 ml) for smaller joints and up to 40 mg (1.0 ml) for larger joints usually give relief of symptoms.

This medicine should not be used for injection into the Achilles tendon.

Use in allergic disorders:

The usual starting dose is 40 mg (1.0 ml) injected deeply into the upper outer area of the buttock. If you require a further injection, this should be made into the same area on the other buttock. Some patients with pollen asthma find that one injection of 40-100 mg improves asthmatic symptoms.

Your doctor will advise you whether it is wise for you to have further injections.

Deep intramuscular injection must be given into the large muscles of the buttock and not into the upper arm or the thigh.

This medicine should not be given into a vein.

If you are receiving long-term intramuscular treatment with Kenalog IA/IM injection your doctor may advise you to eat more protein. This should help to reduce the gradual loss of weight that can sometimes occur with long-term treatment.

Treatment with steroids is usually kept as short as possible and must not be stopped abruptly. Joints may become permanently damaged by repeated injections over a long period of time.

When the treatment is stopped you may notice flu-like symptoms, runny nose or itchy eyes or skin.

During times of illness or stress, patients on long-term treatment may require the addition of oral steroid tablets, or, if they have recently finished a course of Kenalog IA/IM injections, may need to start taking oral steroid tablets for a while.

Mental health problems while taking Kenalog IA/IM injection

Mental health problems can happen while taking steroids like Kenalog IA/IM Injection (see also section 4 Possible Side Effects).

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen they might need treatment.

Talk to a doctor if you (or someone taking this medicine), shows any signs of mental health problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or stopped.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious effects: tell a doctor straight away

Steroids including Kenalog IA/IM injection can cause serious mental health problems. These are uncommon in both adults and children.

- Mood changes, mental health disorders, feeling dependent on the medicine, trouble sleeping, fits or epilepsy, fainting and dizziness
- Feeling depressed, including thinking about suicide.
- Feeling high (euphoria and mania) or moods that go up and down.
- Feeling anxious/irritable, having problems sleeping, difficulty in thinking or being confused and losing your memory.
- Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of the following side effects **talk to a doctor straight away**.

Serious cases of anaphylactic reactions (i.e. a serious allergic reaction) and anaphylactic shock including death have been reported. If you notice any of the following, **contact your doctor immediately:**

- Swelling of the face, lips or throat
- Breathing difficulties
- Skin itching, redness or a rash

As these may be signs of an allergic reaction

Common: may affect up to 1 in 10 people

- Increased risk of infection
- Injection site reactions
- Headache
- Joint pain

Uncommon: may affect up to 1 in 100 people

- Changes in blood chemicals, which can cause fluid retention
- Heart failure or irregular heart beat
- Weak or fragile bones or muscles, poor healing of broken bones or destruction of the ends of bones, decrease in muscle mass, muscle or bone pain, muscular weakness/discomfort, bone fracture
- Loss of bone tissue (osteoporosis)
- Thin/fragile skin, rashes, stretch marks, bruising, sweating, flushing and increased hair growth, itchy bumps, loss/darkening of skin colour
- Indigestion, stomach pain, stomach ulcers and perforation, bloating, increased appetite and weight loss, inflammation of the pancreas/oesophagus, stomach bleeding
- Eye problems including inflammation, glaucoma and cataracts, blindness, bulging of the eye, damage to the cornea or white of eye
- Infection of the nose
- Irregular periods/ postmenopausal women may also experience vaginal bleeding
- Fungal or Viral eye infections
- Yeast infections e.g. thrush
- Tiredness and tingling, Increased pressure in the brain
- Increased appetite
- Weight loss
- Less tolerance to carbohydrates
- Mild form of diabetes with no obvious symptoms
- Inadequately controlled diabetes mellitus, high blood sugar
- Pain, swelling and worsening of the pain in the injected joint
- Impaired healing
- High body temperature
- Treatment with steroids can stop the body from producing some hormones and may slow or stop children's growth.
- Hormone production by certain glands may be increased or decreased.
- Vertigo
- High/low blood pressure
- Abnormal blood clots

- Longstanding chronic infections such as tuberculosis could be made worse

Not known: frequency cannot be estimated from available data

- Blurred vision
- Central serous chorioretinopathy

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kenalog IA/IM Injection

Keep this medicine out of the sight and reach of children.

Kenalog IA/IM injection will be kept in the pharmacy until it is given to you by your doctor or nurse.

It should not be used after the expiry date shown on the outer packaging.

It should not be stored above 25°C nor should it be allowed to freeze.

The container should be kept in the outer carton.

6. Content of the pack and other information

What Kenalog IA/IM injection contains

The active substance is triamcinolone acetonide 40 mg/ml.

The other ingredients are; benzyl alcohol, polysorbate 80, carmellose sodium, sodium chloride and water.

Kenalog IA/IM Injection belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Kenalog IA/IM Injection) is an effective way to treat various illnesses involving inflammation in the body. Kenalog IA/IM Injection reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

What Kenalog IA/IM injection looks like and contents of the pack

Kenalog IA/IM injection is a sterile aqueous suspension for injection and is supplied in 1.0 ml glass vials.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER

Marketing Authorisation Holder

Bristol-Myers Squibb Pharmaceuticals Unlimited Company
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This leaflet was revised in September 2023