

Package leaflet: Information for the user
Adcortyl Intra-articular / Intradermal Injection 10 mg/ml Suspension for Injection
Triamcinolone acetonide

Read all of this leaflet carefully before you are given 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.

- **Adcortyl IA/ID 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 using this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Adcortyl IA/ID 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 using your medicine, **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 are given this medicine for more than 3 weeks, you will be given a blue 'steroid card'**: always keep it with you and show it 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

1. What Adcortyl IA/ID Injection is and what it is used for
2. What you need to know before you are given Adcortyl IA/ID Injection
3. How to use Adcortyl IA/ID Injection
4. Possible side effects
5. How to store Adcortyl IA/ID Injection
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1. What Adcortyl IA/ID Injection is and what it is used for

The name of this medicine is Adcortyl IA/ID Injection. Each injection contains triamcinolone acetonide 10 mg/ml as the active ingredient. Triamcinolone acetonide belongs to a group of medicines called corticosteroids (steroids). These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Adcortyl IA/ID Injection) is an effective way to treat various illnesses involving inflammation in the body. Adcortyl IA/ID 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. Adcortyl IA/ID Injection is for the treatment of joint pain, swelling and stiffness in inflammatory disorders such as rheumatoid arthritis, osteoarthritis

and psoriasis. It is also used to treat various forms of allergic dermatitis, skin overgrowths such as thickened scar tissue, and patchy baldness, which is usually reversible.

2. What you need to know before you are given Adcortyl IA/ID Injection

Do not receive Adcortyl IA/ID Injection if;

- You have had an **allergic** reaction to a similar medicine or any of the ingredients in this medicine
- You are suffering from an **infection** unless your doctor has also prescribed a treatment for the infection.
- Have had any recent infection (including tuberculosis (TB))
- Have had recent bowel surgery
- Have, or have had a bowel disorder or stomach ulcer
- Suffer from any condition that affects your mind

Adcortyl IA/ID Injection is not recommended for children under 6 years.

You must tell your doctor if you:

- Have had liver failure
- Have had chickenpox or measles recently
- Have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely
- Have an infection or inflammation of the veins in your legs
- Have had any mental health disorders or epilepsy
- Have had any kidney, liver or thyroid problems as the dose of Adcortyl may need to be adjusted
- Have recently suffered from any form of cancer
- Have thin or brittle bones (osteoporosis)
- Have myasthenia gravis (a disease which causes weak muscles)
- Have a disease that causes a serious rash (exanthematous)
- Have high blood pressure or heart failure
- Or someone in your family has glaucoma (increased pressure in your eyes).
- Have blurred vision or other visual disturbances, loss of vision, eye inflammation and viral retinitis (inflammation of retina caused mainly by cytomegalovirus).
- Are diabetic as your insulin dose may need to be changed
- If you have ever suffered from steroid myopathy (damage to your muscle fibers caused by treatment with corticosteroids)
- If you have an underactive thyroid gland
- If you are going through the menopause

Check with your doctor first:

- **If you have ever had severe depression** or manic-depression (bipolar disorder).
This includes having had depression before or while taking steroid medicines like Adcortyl IA/ID Injection.
- If any of your close family has had these illnesses.
If either of these applies to you, **talk to a doctor before Adcortyl IA/ID Injection is given to you.**

Caution is advised in taking triamcinolone acetonide (**Adcortyl IA/ID Injection**) and medicines to control HIV (anti-retrovirals) or fungal infections (anti-fungals) because you could experience more

adverse effects. Refer to list of medicines mentioned in “Taking other medicines with Adcortyl IA/ID 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 first.

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

Taking other medicines with Adcortyl IA/ID 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: Caution is advised in co-administration of ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, ketoconazole, and telithromycin with triamcinolone because increased adverse effects may occur, resulting in whole body corticosteroid effects including Cushing’s syndrome and reduction in hormone production
- 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
- Potassium depleting medicines.
- Diuretics e.g. acetazolamide, loop diuretics, thiazide diuretics and carbenoxolone.
- Barbiturates, carbamazepine, primidone and aminoglutethimide
- Any non-depolarising muscle relaxants to provide relaxation for surgery or medicines to treat;
- Medicine for High blood pressure or irregular heart beat (e.g. digoxin)
- Medicine for Myasthenia gravis (a disease which causes weak muscles)
- Medicine for Epilepsy or fits (e.g. phenytoin)
- Medicine for Tuberculosis (TB)
- Medicine for Diabetes
- Medicine for Thyroid problems

If you are taking any of these medicines, have had any recent vaccinations, need to have a vaccine 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 Adcortyl IA/ID injection.

Pregnancy and breastfeeding

If you are pregnant, planning to become pregnant, or if you are breast-feeding you should discuss this with your doctor as soon as possible before receiving Adcortyl IA/ID 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 or problems with your vision.

Steroid Treatment Card

Your doctor or pharmacist will have given you a Steroid Treatment Card with your prescription or medicine.

YOU SHOULD ALWAYS CARRY THIS CARD WITH YOU as it 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 Adcortyl IA/ID Injection

Adcortyl IA/ID Injection contains 15 mg/ml benzyl alcohol which may cause harmful or allergic reactions in infants and children up to 3 years old. Adcortyl IA/ID injection must not be given to premature or newly born babies.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Adcortyl IA/ID 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.

Adcortyl is not suitable for injection into the vein, muscle, eye or spine

Use in inflammatory joint disorders:

The dose of injection to be given 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 2.5 – 5 mg (0.25-0.5 ml) for smaller joints and 5-15 mg (0.5-1.5 ml) for larger joints usually give relief of symptoms. This medicine should not be used for injection into the Achilles tendon.

Use in allergic dermatitis:

The dose is usually 2-3 mg (0.2-0.3 ml) depending on the size of the problem area of the skin but no more than 5 mg (0.5 ml) should be injected at any one site. If several sites are injected the total dose given should not exceed 30 mg (3 ml). Further doses may be given if necessary at one or two week intervals.

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

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 Adcortyl IA/ID injections, may need to start taking oral steroid tablets for a while.

Children

Adcortyl IA/ID injections, is not recommended in children under 6 years. It may be given to older children in suitably adjusted dosages.

Growth and development should be carefully observed during long term treatment.

Elderly

Long term treatment should be supervised to avoid life threatening reactions.

Method of 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.

Mental health problems while Adcortyl IA/ID injection is given to you

Mental health problems can happen while taking steroids like Adcortyl IA/ID Injection (see 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 who has been given 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, Adcortyl IA/ID injection can cause side effects, although not everybody gets them.

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

Tell your doctor immediately if you notice any sticky black stools, get severe abdominal pain or if you vomit blood.

Steroids including Adcortyl IA/ID injection can cause serious mental health problems.

These are uncommon in both adults and children. If you notice any of these problems **talk to a doctor straight away**:

- 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.

Common: may affect up to 1 in 10 people

- Increased risk of infection
- Headache
- Injection site reactions, including temporary worsening of pain in the injected joint

Uncommon: may affect up to 1 in 100 people

- Changes in blood chemicals which can cause fluid retention
- Heart failure or irregular heart beat
- High blood pressure
- Abnormal blood clots
- Weak or fragile bones or muscles, bone fracture, poor healing of broken bones, decrease in muscle mass, muscle or bone pain, destruction of the ends of bones, tendon rupture
- Thin/fragile skin, rashes, inflamed/itchy skin, skin swelling, flushing, loss/darkening of skin colour, acnes, stretch marks, bruising, sweating, increased hair growth
- Fits or epilepsy, fainting, dizziness and increased pressure in the brain.
- Indigestion
- Stomach ulcers and perforation, bloating, inflammation of the pancreas, inflammation and ulceration of the oesophagus.
- Eye problems including inflammation, glaucoma and cataracts, blindness, bulging of the eye, damage to the cornea or white of the eye
- Fungal or Viral eye infections
- Yeast infections e.g. thrush
- Vertigo
- Tiredness, tingling-and numbness
- Pain, swelling and skin colour changes around the injection site
- Impaired wound healing
- Loss of bone tissue (osteoporosis) or death of bone tissue caused by loss of blood supply to the bone (osteonecrosis)
- Development of a red moon shaped face or wasting of the limbs
- 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.
- Increased appetite and weight gain
- Less tolerance to carbohydrates
- Mild form of diabetes with no obvious symptoms
- Inadequately controlled diabetes mellitus, high blood sugar
- Irregular periods/Postmenopausal women may also experience vaginal bleeding.

- Worsening of existing mental health disorders and feeling dependent on the medicine
- Effect on tissue fat at injection site (can appear as dimples)
- Longstanding chronic infections such as tuberculosis could be made worse

Not known: frequency cannot be estimated from the available data

- Blurred vision
- Visual impairment

Withdrawal symptoms which can include, psychiatric effects, fever, joint and muscle pain, runny nose, eye infection, painful itchy skin nodules and weight loss may occur.

A rapid reduction in dose following prolonged treatment can lead to acute adrenal insufficiency, low blood pressure and death.

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:

HPRAs Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Adcortyl IA/ID Injection

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

Do not use this medicine after the expiry date shown on the label and carton. The expiry date refers to the last day of that month. The expiry date refers to the last day of that month.

Store between 15°C-25°C. Do not freeze or refrigerate. Store in the outer carton to protect from light.

Store in an upright position. Shake well before use.

Once opened,

Adcortyl IA/ID Injection (1 ml) is for single-use only. Discard any unused contents immediately after use.

Adcortyl IA/ID Injection (5 ml) Once in use: Chemical and physical in-use stability has been demonstrated for 28 days below 25°C.

From a microbiological point of view, once opened, the product may be stored for a maximum of 28 days at 15-25°C.

Other in-use storage times and conditions are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Content of the pack and other information

What Adcortyl IA/ID injection contains

The active substance is triamcinolone acetonide 10 mg/ml.

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

What Adcortyl IA/ID injection looks like and contents of the pack

Adcortyl IA/ID injection is a white sterile aqueous suspension with a slight odour.
It is supplied in packs of 5 x 1 ml glass ampoules or a single 5 ml glass vial.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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