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.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

1. WHAT ADCORTYL 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. BEFORE YOU ARE GIVEN YOUR MEDICINE

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 an infection or inflammation of the veins in your legs
• Have had any mental 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 high blood pressure or heart failure
• Or someone in your family has glaucoma (increased pressure in your eyes).
• 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

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.

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
Always tell your doctor about any medicines you are taking, or have recently taken, including those obtained without a prescription.
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.
– Any antifungals (e.g. ketoconazole, amphotericin)
– 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 eg acetazolamide, loop diuretics, thiazide diuretics and carbenoxolone.
– Barbiturates, carbamazepine, primidone and aminogluthethimide
– Any nondepolarising muscle relaxants to provide relaxation for surgery or medicines to treat;
– High blood pressure or irregular heart beat (e.g. digoxin)
– Myasthenia gravis (a disease which causes weak muscles)
– Epilepsy or fits (e.g. phenytoin)
– Tuberculosis (TB)
– Diabetes
– Thyroid problems
or if you have had any recent vaccination.
If you are taking any of these medicines, have had any vaccinations 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 or operating machinery**
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
Adcortyl IA/ID Injection contains 15mg/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. RECEIVING YOUR MEDICINE
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 intravenous, intramuscular, intraocular, epidural or intrathecal use.

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 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.
Mental problems while Adcortyl IA/ID injection is given to you
Mental health problems can happen while taking steroids like Adcortyl IA/ID 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 who has been given this medicine), shows any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

4. POSSIBLE SIDE EFFECTS
As with all medicines, Adcortyl IA/ID injection can cause unwanted side effects, although not everybody gets them.
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
Serious cases of anaphylactic reactions and anaphylactic shock including death have been reported.

Tell your doctor immediately if you notice any sticky black stools, get severe abdominal pain or if you vomit blood.
Other side effects of Adcortyl IA/ID injection include:
– Increased risk of infection
– Changes in blood chemicals which can cause fluid retention, heart failure or irregular heart beat
– High blood pressure
– Weak or fragile bones or muscles, poor healing of broken bones or torn muscles, destruction of the ends of bones, loss of muscle mass
– Thin skin, rashes, acres, stretch marks, bruising, sweating, flushing and increased hair growth
– Increased risk of bone structure
– Mood changes, worsening of existing mental disorders, feeling dependent on the medicine, trouble sleeping, headaches, fits or poor control of epilepsy, fainting and dizziness.
– Indigestion, stomach pain, stomach ulcers and perforation, bloating, increased appetite and weight gain, inflammation of the pancreas, inflammation and ulceration of the oesophagus.
– Eye problems including glaucoma and cataracts
– Irregular periods
– Fungal infections e.g. thrush
– Tiredness and tingling and numbness
– Pain and skin colour changes around the injection site and temporary worsening of the pain in the injected joint
– Very rare instances of blindness have been reported following injection to the face.
– Impaired wound healing
– Loss of bone tissue (osteoporosis)
– Development of a red moon shaped face or wasting of the limbs
– Suppression of growth in childhood and adolescence
– Less tolerance to carbohydrates
– Mild form of diabetes with no obvious symptoms
– Increased need for insulin or agents to help lower blood sugar levels
– Weight gain
– Withdrawal symptoms which can include, 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.
Postmenopausal women may also experience vaginal bleeding.

**Serious effects: tell a doctor straight away**
Steroids including Adcortyl IA/ID injection can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people who have been given medicines like Adcortyl IA/ID injection.
• Feeling depressed, including thinking about suicide.
• Feeling high (mania) or moods that go up and down.
• Feeling anxious, 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 these problems **talk to a doctor straight away**.
Treatment with steroids can stop the body from producing some hormones and may slow or stop children’s growth.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**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

IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: [www.imb.ie](http://www.imb.ie)
e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.
5. HOW TO STORE YOUR MEDICINE
Keep out of reach and sight of children.
Adcortyl IA/ID (1 ml) is for single-use only. Discard any unused contents immediately after use.
Adcortyl IA/ID (5 ml) once opened, the product may be stored for a maximum of 28 days below 25°C. Other in-use storage times and conditions are the responsibility of the user.
Adcortyl IA/ID 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 label and carton.
The expiry date refers to the last day of that month.
It should not be stored above 25°C .
Do not freeze or refrigerate. Protect from light
Store in an upright position. Shake well before use.
The container should be kept in the outer carton.
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. FURTHER 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.
Adcortyl IA/ID injection is a white sterile aqueous suspension with a slight odour.
It is supplied in packs of 5 x 1.0 ml glass ampoules or a single 5 ml glass vial.

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