This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- how you should take your medicine
- the possible side effects
- what tests you will have to monitor your condition
- other precautions you should take while you are receiving treatment with anakinra.

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking anakinra you must see your rheumatologist regularly to ensure the treatment is working and to minimise any possible side effects.
- If you stop anakinra for any reason you must contact your doctor.
- Remember to change the injection site each time anakinra is injected.
- If you are worried about any side effects you should contact your rheumatologist as soon as possible.
- It is important to tell your doctor if you have had cancer or if you develop cancer.
- If you are taking anakinra and plan to become pregnant you must discuss the timing with your doctor.

For more information about RHEUMATOID ARTHRITIS see the Arthritis Australia website www.arthritisaustralia.com.au

What is anakinra?

Anakinra (brand name Kineret) belongs to a new class of medicines called biological disease modifying antirheumatic drugs (biological DMARDs).

bDMARDs have now been given to over a million people worldwide since their initial use in the late 1990s.

These medicines block natural substances called cytokines, which are found in excessive amounts in the joints of people with rheumatoid arthritis or juvenile/childhood arthritis.

The increased levels of cytokines cause inflammation that results in symptoms of pain, joint swelling and stiffness, and can lead to joint damage.

By blocking the cytokine called Interleukin 1, anakinra reduces inflammation, lessens the symptoms and helps stop further joint damage.

Anakinra was removed from the PBS on 1 December 2010. Anakinra is therefore not a government subsidised bDMARD for rheumatoid arthritis or juvenile arthritis.

What benefit can you expect from your treatment?

Unlike standard antirheumatic drugs (DMARDs), anakinra works relatively quickly and some relief of joint swelling, pain and stiffness may be noticed within the first 4 to 6 weeks.

Stopping anakinra

If you stop anakinra treatment for more than a few days there is a risk that your condition will get worse again. Continue with your treatment unless advised by your doctor or unless side effects develop (see Side effects).

If you stop anakinra for any reason you must contact your doctor.
How will your condition be monitored?

In view of the current prescribing restrictions for all bDMARDs:

- Anakinra will only be started if your disease is active and if standard treatments have been unsuccessful.
- It will not be continued unless it helps your condition.
- Blood tests will be required during your treatment to monitor your condition and to determine the effectiveness of treatment.
- The frequency of blood tests will depend on what other medicines you are taking and what other illnesses you might have. Your rheumatologist will determine the frequency of tests required.

Most common possible side effects

- Mild pain, swelling or itching are very common (up to 20% of patients) but can be reduced by applying ice and antihistamine/steroid creams to the injection site.
- Headaches, cough and stomach and bowel discomfort may also occur.
- As anakinra affects the immune system, mild infections, particularly of the upper respiratory tract (e.g. colds, sinusitis) may occur more frequently than usual. Treatment with anakinra may need to be temporarily stopped so you should contact your doctor for advice.

Less common or rare possible side effects

- Anakinra can cause a drop in the number of white blood cells, which are needed to fight infection.
- It can cause infections such as pneumonia, skin or joint infections. These effects can occur even if there is no effect on the white blood cells.
- Rarely anakinra may cause an allergic reaction with itchy, red skin or a rash, tightness in the chest and difficulty breathing.
- It is still unclear from research if there is an increased risk of cancer due to anakinra (see Precautions).

What precautions are necessary?

Infections

- If you have an active infection of any kind, treatment with anakinra will not be given until the infection is treated successfully.
- Anakinra will not be given if you have active untreated tuberculosis (TB) or HIV (AIDS) infection as it is likely to make these conditions worse.
- If you have latent (inactive) TB preventative anti-TB treatment will be started at least 4 weeks before anakinra. The anti-TB treatment will usually need to be taken for 9 months.
- Hepatitis B or C infection may not necessarily exclude treatment.
- Because of the risks associated with infection, the following tests may be conducted before commencing treatment with anakinra:
  - blood tests for hepatitis B and C

How is anakinra taken?

Anakinra is given as an injection under the skin of the abdomen or thigh.

It can be injected by your doctor, nurse or carer, or by you. If injecting yourself, be sure to follow the detailed instructions carefully to ensure the best response. It is particularly important to change the injection site each time.

What is the dosage?

The usual dose for adults is 100mg once a day.

Can other medicines be taken with anakinra?

Anakinra may be used with other arthritis medicines including:

- other DMARDs such as methotrexate
- steroid medicines such as prednisolone or cortisone injections into the joint
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen, Nurofen)
- simple pain medicines such as paracetamol.

Anakinra cannot be used with other biological DMARDs.

There are separate information sheets for the medicines mentioned above.

Are there any possible side effects?

You might experience side effects with your treatment. Contact your doctor if you have any concerns about possible side effects. Many side effects disappear when anakinra treatment is stopped.
- chest x-ray and two step Tuberculin Skin Test (Mantoux) or QuantiFERON blood test for tuberculosis (TB)
- HIV tests are required for those who are at risk of this infection.

**Use with other medicines**

- Anakinra can interact with other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.
- You should also mention your treatment when you see other health professionals.
- Anakinra does not increase the risk of side effects from low dose aspirin (taken for prevention of heart attack and strokes).
- The simple pain reliever paracetamol and combined pain medicines such as Panadeine and Panadeine Forte can be used while you are receiving anakinra treatment provided you take them as directed.

**Vaccines**

- If you are on anakinra it is recommended you should not be immunised with ‘live’ vaccines such as MMR (measles, mumps and rubella), OPV (oral polio virus), BCG (Bacillus Calmette-Guerin) or yellow fever. Talk with your rheumatologist before receiving any vaccines.
- Pneumovax and the combined yearly seasonal flu/swine flu vaccinations are safe and recommended to reduce your risk of those infections.

**Surgery**

- If you require surgery for any reason, treatment with anakinra will be stopped before the surgery. It will be restarted after the operation at a time determined by your surgeon and rheumatologist. Treatment will be restarted once the wound is healed and if there is no infection present.

**Cancer risk**

- Lymphoma, a cancer of lymph glands, is found more commonly in patients with severe active rheumatoid arthritis than in the general population. Studies are in progress to see if treatment with anakinra changes this. To date there is no evidence to suggest that this medicine increases lymphoma.
- If cancer has been previously treated and cured it is unclear whether a bDMARD such as anakinra can be used safely. An interval of 5 years is normally recommended between cure of a cancer and starting TNF-bDMARDs.
- For general cancer prevention, stopping smoking and taking skin cancer prevention measures are recommended. It is important to use sunscreen and avoid prolonged sun exposure. A yearly skin check is recommended.
- Talk to your doctor if you have any concerns about issues relating to cancer risk.

**Use with alcohol**

- You may drink alcohol while taking anakinra. However, if you are also taking methotrexate you should be particularly cautious about your alcohol intake.
- It is not known precisely what level of drinking is safe when on methotrexate, however there is general agreement that 1 to 2 standard drinks taken once or twice a week is unlikely to cause a problem.
- Drinking more than 4 standard drinks on one occasion, even if infrequently, is strongly discouraged.

**Pregnancy and breastfeeding**

- Not enough is known about the possible side effects of anakinra on the unborn baby. If you plan to become pregnant it is important to discuss this with your doctor as each case is different.
- You should not breastfeed when taking anakinra.

**How to store anakinra**

- Keep the medicine refrigerated, even when travelling.
- Keep all medicines out of reach of children.
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The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.