PATIENT INFORMATION ON

TOCILIZUMAB

(Brand name: Actemra)

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 taking tocilizumab.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking tocilizumab you must see your rheumatologist regularly to ensure the treatment is working and minimise any possible side effects.
- If you stop tocilizumab for any reason you must contact your doctor. Failure to do so may mean that your continued treatment will no longer be subsidised.
- 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 while you are taking tocilizumab.
- If you are taking tocilizumab 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 tocilizumab?

Tocilizumab (brand name Actemra) belongs to a new class of medicines called **biological disease modifying antirheumatic drugs (biological DMARDs or bDMARDs).**

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 blood and joints of people with rheumatoid arthritis.

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

By blocking the cytokine called interleukin-6 (IL-6) tocilizumab reduces inflammation, lessens the symptoms and helps stop further joint damage.

Tocilizumab is also used to treat juvenile idiopathic arthritis.

What benefit can you expect from your treatment?

Unlike many standard antirheumatic drugs (DMARDs) tocilizumab works relatively quickly. You may notice some relief of joint swelling, pain and stiffness within the first eight weeks of treatment.

Stopping tocilizumab

If tocilizumab treatment is stopped for more than a few weeks 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 tocilizumab for any reason you **must** contact your doctor. Failure to do so may mean that your continued treatment may no longer be subsidised.

How will your condition be monitored?

In view of the current prescribing restrictions for all bDMARDs:

- Tocilizumab will only be given if your disease is active and if standard treatments have been unsuccessful.
- It will not be continued unless it helps your condition. This will be assessed at least 12 weeks after the start of treatment.
- 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.

How is tocilizumab taken?

Tocilizumab may be given as a drip (infusion) into the vein or as a subcutaneous (under the skin) injection in the abdomen or thigh. The injections under the skin are given weekly and the infusion is given every four weeks. The infusion normally takes one hour.

The first injection or infusion will be followed by a period of observation for at least one hour to make sure you don't have any side effects. After the first dose, your doctor may discuss whether you wish to inject further doses yourself.

If injecting yourself, be sure to follow the instructions carefully and change the injection site each time. Ask your doctor if you have any questions before starting the injections.

What is the dosage?

For people having tocilizumab every four weeks as a drip into a vein, the dose is based on body weight so each person's dose may be different. For people having tocilizumab as an injection under the skin, the dose is usually 162mg (one pre-filled syringe).

Can other medicines be taken with tocilizumab?

Tocilizumab 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.

There are separate information sheets for the medicines mentioned above.

Tocilizumab cannot be used with other bDMARDs.

Are there any side effects?

You might experience side effects with your treatment. Contact your doctor if you have any concerns about possible side effects.

Most common possible side effects

- Side effects can occur during the infusion itself. These may include *fever or chills, itch, dizziness, headache, chest pain, shortness of breath* or *changes in blood pressure*. These effects are more likely to occur during the first or second infusion and can usually be reduced by giving steroids, antihistamines and paracetamol before the treatment.
- Other common possible side effects include:
  - *headache or cough*
  - *stomach or bowel discomfort*
  - *skin effects* such as rash, dermatitis and itching may occur in up to 10% of patients. These are usually mild, and do not usually require stopping treatment.
- *Liver enzymes*: Tocilizumab can cause liver tests to rise in up to 40% of patients. The tests returned to normal in most patients while they were still being treated with the medicine. This does not cause symptoms unless severe so regular blood tests are important.
- *Cholesterol level:* Tocilizumab may cause a reversible increase in cholesterol and triglyceride levels. While high cholesterol and triglyceride levels are risk factors for heart attack and stroke, the long-term

significance of this in patients with rheumatoid arthritis is uncertain.

- As tocilizumab affects the immune system *mild infections,* particularly of the upper respiratory tract (e.g. colds, sinusitis) may occur more frequently than usual. Treatment may need to be temporarily stopped so contact your doctor for advice.

Less common or rare possible side effects

- *Blood counts*: Tocilizumab can cause a drop in the number of white blood cells, which are needed to fight infection. This is monitored carefully with regular blood tests.
- *Serious infections* such as tuberculosis (TB) are seen rarely and screening for TB is needed before treatment begins (see below).
- *Perforation of the stomach or gut* (a hole in the bowel wall) has been reported rarely in patients treated with tocilizumab.
- It is still unclear from research if there is an increased risk of cancer due to tocilizumab treatment (see *Precautions*).

What precautions are necessary?

Infections

- If you have an active infection of any kind treatment with tocilizumab will not be given until the infection is treated successfully.
- Tocilizumab 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 four weeks before tocilizumab. The anti-TB treatment will usually need to be taken for nine 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 tocilizumab:
  - blood tests for hepatitis B and C
  - 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.

Precautions with other diseases

- People with diverticular disease may not be treated with tocilizumab as the medicine may increase risk of perforations.

Use with other medicines

- Tocilizumab 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.
- Tocilizumab 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 tocilizumab treatment provided you take them as directed.

Vaccines

- If you are on tocilizumab 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 tocilizumab will be stopped before surgery. It will be restarted again 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.

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Use with alcohol

- You may drink alcohol while taking tocilizumab. However, if you are also taking methotrexate you should be 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 one to two standard drinks taken once or twice a week is unlikely to cause a problem.
- Drinking more than four standard drinks on one occasion, even if infrequently, is strongly discouraged.

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 tocilizumab changes this risk. 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 tocilizumab can be used safely. An interval of five 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 in pregnancy and when breastfeeding

- Not enough is known regarding the possible effects of tocilizumab 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 tocilizumab.

How to store tocilizumab

- Store tocilizumab in a refrigerator (2 to 8°C). Do not freeze.
- Keep all medicines out of reach of children.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

If you are taking tocilizumab you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.