



Australian
Rheumatology
Association

PATIENT INFORMATION ON

ABATACEPT

(Brand name: Orencia)

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;
- What are the possible side effects;
- What tests you **must** have to monitor your condition and to detect unwanted effects; and
- Other precautions you should take.

Please read it carefully and discuss with your doctor.

What is abatacept?

Abatacept (brand name Orencia) belongs to a new class of medicines called **biological disease modifying antirheumatic drugs (biological DMARDs)**.

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 these substances, abatacept reduces inflammation, lessens the symptoms and helps stop further joint damage.

For more information about RHEUMATOID ARTHRITIS see the Arthritis Australia website www.arthritisaustralia.com.au/index.php/arthritismodifying-information/information-sheets.html.

What benefit can you expect from your treatment?

Unlike standard DMARDs, abatacept works relatively quickly and some relief of joint

swelling, pain and stiffness may be noticed within the first 4 weeks of treatment.

If abatacept treatment is stopped for more than a few weeks there is a risk that your condition may worsen. Continue with your treatment unless advised by your doctor or unless side effects develop.

Current Australian prescribing restrictions for all biological DMARDs mean abatacept will only be given if your disease is active and standard treatments have been unsuccessful.

It will also only be continued if the response is adequate. Initial response will be assessed at least 12 weeks after the start of treatment.

How is abatacept given?

Abatacept is given as a drip (infusion) into the vein. The infusion normally takes thirty minutes and is followed by a period of observation for at least one hour to make sure you don't have any side effects.

Additional doses are usually given at 2 and 4 weeks after the first dose. Subsequent doses are usually given every 4 weeks.

Abatacept is given in combination with the DMARD methotrexate.

Abatacept may be used with other arthritis medicines including:

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

It should not be given with other biological DMARDs.

Are there any side effects?

Biological DMARDs have now been given to over 750,000 people worldwide since initial use in the late 1990s.

Below are side effects that you might experience with your treatment. Tell your doctor if you experience any 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:
 - *headaches, runny nose, dizziness or cough;*
 - *sore throat, heartburn or nausea;*
 - *back, arm or leg pain;*
 - *urine infections;*
 - *rash.*
- As abatacept affects the immune system, *mild infections*, particularly of the upper respiratory tract (e.g. colds, sinusitis) may occur more frequently than usual.

Tell your doctor if you experience any possible side effects.

Less common or rare possible side effects:

- *Serious infections* such as Tuberculosis (TB) are seen rarely and screening for TB is needed before treatment begins (see below).
- *Cancer:*
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 abatacept changes this. Currently there seems no suggestion of any increase in cancer with abatacept.
If cancer has been previously treated and cured it is unclear whether a TNF-biological DMARD such as abatacept can be used safely. At present an interval of at least 5 years is recommended between cure of a cancer and starting TNF-biological DMARDs.

For general cancer prevention, stopping smoking is recommended, so too are skin cancer prevention measures (see *Precautions* overleaf).

Talk to your doctor, if you have any concerns about issues relating to cancer risk.

What precautions are necessary?

Infections:

- Abatacept should 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 4 to 6 weeks before abatacept. The anti-TB treatment may need to be taken for up to 9 months.
- Hepatitis B infection also presents a risk in this regard, but you may still be able to receive treatment with abatacept. This medicine can usually be given safely if you have Hepatitis C.
- The following tests are required before commencing treatment with abatacept:
 - blood tests for Hepatitis B and C;
 - chest x-ray and two step Tuberculin Skin Test (Mantoux) or QuantiFERON assay for tuberculosis (TB).
- HIV tests are required only for those at risk of this infection.
- If you have an active infection of any kind, treatment with abatacept will not be given until the infection is treated successfully.

Ongoing blood tests:

- 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.

Other medicines:

- Abatacept 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.

