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**
- **the possible side effects**
- **what tests you will have to monitor your condition and detect unwanted effects**
- **other precautions you should take while you are taking abatacept**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking abatacept you must see your rheumatologist regularly to ensure the treatment is working and to minimise any possible side effects.
- If you stop abatacept for any reason you must contact your doctor. Failure to do so may mean that your continued treatment may no longer be subsidised.
- If you are worried about any side effects you should contact your rheumatologist as soon as possible.
- If you are injecting abatacept under the skin (subcutaneously) remember to change the injection site each time.
- It is important to tell your doctor if you have had cancer or if you develop cancer.
- If you are taking abatacept 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/index.php/arthritis-information/information-sheets.html.

What is abatacept?

Abatacept (brand name Orencia) 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. These are substances found in excessive amounts in the blood and joints of people with rheumatoid arthritis and juvenile 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 T cell (a type of white blood cell) responses, abatacept reduces inflammation, lessens the symptoms and helps stop further joint damage.

What benefit can you expect from your treatment?

Unlike standard antirheumatic drugs (DMARDs), abatacept works relatively quickly. You may notice some relief of joint swelling, pain and stiffness within the first 4-8 weeks of treatment.

Stopping abatacept

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 (see *Side effects*).

If you stop abatacept 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:

- Abatacept 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. 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 abatacept given?

Abatacept is given as a drip (infusion) into the vein, or as an injection under the skin of the abdomen or thigh.

The infusion normally takes thirty minutes. This is followed by a one hour period of observation 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.

When given as an injection under the skin (subcutaneous injection), doses are given weekly.

The treatment may still begin with a single dose given as an infusion (loading dose).

Abatacept is given in combination with the DMARD methotrexate.

What is the dosage?

For infusions the dose is based on the person's weight, so each person's dose may be different.

The subcutaneous dose is a standard 125mg weekly injection.

Can other medicines be taken with abatacept?

Abatacept 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.

Abatacept cannot be used with other bDMARDs.

There are separate information sheets for the medicines mentioned above.

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. Many side effects disappear when abatacept treatment is stopped.

Most common possible side effects

- Common possible side effects include:
  - *headaches, runny nose, dizziness or cough*
  - *sore throat, heartburn or nausea*
  - *back, arm or leg pain*
  - *urine infections*
  - *rash.*
- *Stomach and bowel discomfort* may also occur.
- As abatacept affects the immune system, *mild infections*, particularly of the upper

respiratory tract (e.g. colds, sinusitis) may occur more frequently than usual. Treatment with abatacept may need to be temporarily stopped so contact your doctor for advice.

Less common or rare possible side effects

- Side effects can occur during the infusion itself. These may include *fever or chills, itch, chest pain, shortness of breath* or *changes in blood pressure*. These effects are more likely to occur during the first or second infusion.
- Mild pain, swelling, bruising or itching may occur at the injection site (for subcutaneous doses). It is therefore important to rotate the injection site.
- *Serious infections* such as tuberculosis (TB) are seen rarely, and screening for TB is needed before treatment begins (see *Precautions*).
- Rarely abatacept may cause an *allergic reaction* with itchy, red skin or a rash.
- It is still unclear from research if there is an increased risk of cancer due to abatacept treatment (see *Precautions*).

What precautions are necessary?

Infections

- If you have an active infection of any kind, treatment with abatacept will not be given until the infection is treated successfully.
- Abatacept 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 abatacept. 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 abatacept:
  - 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 chronic lung disease (COPD) are not usually given abatacept but each case will be assessed individually.

Use with 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.
- Abatacept 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 abatacept treatment provided you take them as directed.

Vaccines

- If you are on abatacept 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 abatacept 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.

Use with alcohol

- You may drink alcohol while taking abatacept. 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.

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 abatacept 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 abatacept 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 in pregnancy and when breastfeeding

- Not enough is known regarding the possible side effects of abatacept. 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 abatacept.

How to store abatacept

- Keep the medicine refrigerated, even when travelling.
- 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 abatacept you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

How to help us help you

Sign up to the ARAD project now

The Australian Rheumatology Association collects information on how well these drugs work and how often they cause problems.

The best way to get this information is from you!

Contact us in any of the following ways:
Email: ARAD@monash.edu
Telephone: Sydney 02 9463 1889
or Melbourne 03 9508 3424
Fax: 1-800-022-730
Visit our website: www.ARAD.org.au