

PATIENT INFORMATION ON GOLIMUMAB

(Brand name: Simponi)

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 will have to monitor your condition**
- **other precautions you should take while you are receiving treatment with golimumab.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking golimumab you must see your rheumatologist regularly to ensure the treatment is working and minimise any possible side effects.
- If you stop golimumab for any reason you must contact your doctor. Failure to do so may mean that your continued treatment will no longer be subsidised.
- Remember to change the injection site each time golimumab 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 while you are taking golimumab.
- If you are taking golimumab and plan to become pregnant you must discuss the timing with your doctor.

For more information about RHEUMATOID ARTHRITIS see Arthritis Australia's Empowered website:

www.empowered.org.au

What is golimumab?

Golimumab (brand name Simponi) 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, psoriatic arthritis, juvenile arthritis and ankylosing spondylitis.

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 Tumour Necrosis Factor (TNF), golimumab reduces inflammation, lessens the symptoms and helps stop further joint damage.

What benefit can you expect from your treatment?

You may notice some relief of joint swelling, pain and stiffness within the first 8 weeks of treatment.

Stopping golimumab

If golimumab 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 golimumab for any reason you **must** contact your doctor. Failure to do so may put your ability to continue on subsidised treatment at risk.

How will your condition be monitored?

In view of the current prescribing restrictions for all bDMARDs:

- Golimumab 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 golimumab taken?

Golimumab is injected under the skin of the abdomen or thigh.

It can be injected by your doctor, nurse, 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 with rheumatoid arthritis is 50mg once every month.

Can other medicines be taken with golimumab?

Golimumab 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 and combined pain medicines such as Panadeine and Panadeine Forte.

Golimumab 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 golimumab treatment is stopped.

Most common possible side effects

- *Mild pain, swelling or itching* at the site of the injection are very common (up to 10% 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 golimumab affects the immune system, *mild infections*, particularly of the upper respiratory tract (e.g. colds, sinusitis) may occur more frequently than usual. Treatment with golimumab may need to be temporarily stopped so contact your doctor for advice.

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 *Precautions*).
- Rarely golimumab may cause an *allergic reaction* with itchy, red skin or a rash or a feeling of tightness in the chest and difficulty breathing.
- Side effects involving the *nerves, such as inflammation of the nerve to the eye*, may also occur very rarely, causing changes in vision or sensation.

- Very rarely '*drug-induced lupus*' has occurred with symptoms of rash, fever and increased joint pain.
- It is still unclear from research if there is an increased risk of cancer due to golimumab treatment (see *Precautions*).

What precautions are necessary?

Infections

- If you have an active infection of any kind, treatment with golimumab will not be given until the infection is treated successfully.
- Golimumab 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 golimumab. 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 golimumab:
 - 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 multiple sclerosis should not be treated with golimumab due to the possible effects on the nerves.
- People with moderate to severe heart failure may not be treated with golimumab as the medicine can make heart failure worse.
- People with systemic lupus erythematosus (lupus/SLE) are not usually given golimumab but each case will be assessed individually.

Use with other medicines

- Golimumab 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.
- Golimumab does not increase the risk of side effects from low dose aspirin (taken for prevention of heart attack and strokes).

Vaccines

- If you are on golimumab 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 golimumab will be stopped before surgery. It will be restarted again after the operation at a time agreed 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 golimumab. 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 golimumab 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 TNF-bDMARD such as golimumab 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 golimumab. 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 golimumab.

How to store golimumab

- Golimumab should normally be kept refrigerated, however if needed, for example when travelling, it may be stored below 25°C for up to 4 weeks.
- 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 golimumab you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

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.