PATIENT INFORMATION ON

BARICITINIB

(Brand names: Olumiant)

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 baricitinib.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking baricitinib you must see your rheumatologist regularly to ensure the treatment is working and minimise any possible side effects.
- If you stop baricitinib 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 baricitinib.
- If you are taking baricitinib and plan to become pregnant you must discuss the timing with your doctor.

For more information about RHEUMATOID ARTHRITIS and other anti-inflammatory conditions see the Arthritis Australia website www.arthritisaustralia.com.au

What is baricitinib?

Baricitinib (brand name Olumiant) belongs to a new class of medicines called **targeted synthetic disease modifying antirheumatic drugs (tsDMARDs).**

Baricitinib blocks an enzyme (Janus Kinase or JAK) which helps the transmission of signals from the surface of a cell which normally will cause increased inflammation. By blocking these signals baricitinib helps reduce inflammation in Rheumatoid Arthritis resulting in less pain, swelling and stiffness and reduced joint damage.

What benefit can you expect from your treatment?

Unlike many standard antirheumatic drugs (DMARDs) baricitinib works relatively quickly. You may notice some relief of joint swelling, pain and stiffness within the first 2 to 4 weeks of treatment.

Stopping baricitinib

If baricitinib 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 baricitinib 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:

- Baricitinib 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 baricitinib taken?

Baricitinib is a tablet taken once a day, with or without food.

What is the dosage?

The usual starting dose of baricitinib is one 4mg tablet, (although your doctor may choose to start a lower dose.) This may be reduced to the 2mg tablet dose if you respond well to treatment. If you have poor kidney function you may begin on the 2mg dose.

Can other medicines be taken with baricitinib?

Baricitinib 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. If you are taking probenecid tell your doctor as you may need a lower dose of baricitinib.

Baricitinib cannot be used with other bDMARDs or tsDMARDS (such as tofacitinib).

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 baricitinib treatment is stopped.

Most common possible side effects

- Baricitinib is associated with an increase in infections. These are mainly viral infections of the upper respiratory tract (nose, throat and sinus infections) and urinary tract infections.
- Gastric upsets are the next most common problem with nausea, vomiting and diarrhea.
- Some people gain weight.
- Blood test abnormalities are common. This can include an increase in some blood components such as platelets and a decrease in others such as two types of white cells and haemoglobin, causing mild anemia. If baricitinib is ceased the blood usually returns to normal.
- Liver and muscle enzyme tests can often become mildly abnormal.
- Your blood fats (lipids) should be checked 12 weeks after starting baricitinib because it can cause a rise in cholesterol.
- You should inform your doctor if you develop increased frequency of passing urine or burning urine suggesting infection, or increased tiredness, or any abnormal infections. Treatment may need to be temporarily stopped so it is important to contact your doctor for advice.

Less common or serious possible side effects

- *Blood counts*: Although abnormalities are usually mild sometimes baricitinib will cause a severe abnormality of your liver or blood.
- *Serious infections* such as tuberculosis (TB) are seen rarely and screening for TB is needed before treatment begins (see below).
- Baricitinib causes an increase in shingles, a painful rash due to reactivation of a dormant chickenpox virus. You should discuss with your doctor the possibility of vaccination for this before starting baricitinib.
- It is still unclear from research if there is an increased risk of cancer due to baricitinib treatment (see *Precautions*).
- There is most likely an increased risk of blood clots in people taking baricitinib, especially in the higher dose (4mg tablet). This is more common if you are overweight, have had a clotting problem before, or are also taking a type of anti-inflammatory drug known as a cox-2 inhibitor (an example is celecoxib (Celebrex).

What precautions are necessary?

Infections

- If you have an active infection of any kind treatment with baricitinib will not be given until the infection is treated successfully.
- Baricitinib 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 baricitinib. 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 baricitinib:
  - 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 a history of blood clots need to discuss with the doctor before starting baricitinib.

Use with other medicines

- Baricitinib 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.
- Baricitinib 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 baricitinib treatment provided you take them as directed.

Vaccines

- If you are on baricitinib 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 baricitinib 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 baricitinib. 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 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 baricitinib 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 baricitinib can be used safely. 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 baricitinib on the unborn baby. If you plan to become pregnant it is important to discuss this with your doctor as each case is different. In general you should not conceive while on the drug and for a week after stopping it.
- You should not breastfeed when taking baricitinib.
- More detailed information is available at https://rheumatology.org.au/gps/documents/ARAPregnancyPrescribingGuidanceupdateApr19.pdf

How to store baricitinib

- Store baricitinib in a cool, dry place, away from direct heat and light.
- Keep all medicines out of reach of children.

Questions?	Your doctor's contact details
If you have any questions or concerns write them down and discuss them with your doctor.	If you are taking baricitinib you should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.