PATIENT INFORMATION ON BARICITINIB

(Brand name: Olumiant®)

[Bear–EE–sit–in–ib]

This information sheet was written by the Australian Rheumatology Association to help you understand baricitinib. It includes important information about:

- **how you should take your medicine**
- **the possible side (harmful) effects**
- **what tests you will have to monitor your condition**
- **other precautions you should take while you are taking baricitinib.**

Please read it carefully and discuss it with your doctor.

IMPORTANT THINGS TO REMEMBER

- You must see your rheumatologist regularly to make sure the treatment is working and check for possible side effects.
- You should have regular blood tests as suggested by your rheumatologist.
- It is important to tell your rheumatologist if you have a new serious illness such as a serious infection, cancer or heart failure.
- If you are worried about any side effects, you should contact your rheumatologist as soon as possible.
- If you stop baricitinib for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.
- If you plan to become pregnant, you must discuss the timing with your rheumatologist

For more information about inflammatory conditions associated with arthritis, see Arthritis Australia's website:
www.arthritisaustralia.com.au

What is baricitinib?

Baricitinib (brand name Olumiant®) is a tablet that belongs to a class of medicines called Janus Kinase (JAK) inhibitors. JAK inhibitors work by blocking signals involved in inflammation. Blocking these signals in rheumatoid arthritis reduces pain, stiffness, swelling and damage in the joints.

What benefit can you expect from your treatment?

You may notice some relief of joint swelling, pain and stiffness within the first 2 to 4 weeks of treatment, though it can take up to 3 months to improve.

Stopping baricitinib

If you stop or delay your baricitinib treatment, your disease may get worse. Keep taking your treatment, unless advised by your rheumatologist to stop or unless serious side effects occur (see Side effects).

If you stop baricitinib for any reason you **must** contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.

How will you be checked while on baricitinib?

- Medicines like baricitinib are very expensive and are highly funded by Medicare. Certain conditions must be met to receive it.
- Baricitinib will only be given if your disease is active and if standard treatments have not worked.
- It will only be kept going if it helps your condition. This will be checked around 12 weeks after the start of treatment.
- Blood tests are needed during your treatment to watch for side effects and to decide if the treatment is working.
- How often you have blood tests will depend on what other medicines you are taking and what other illnesses you have. Your rheumatologist will advise on this.

How is baricitinib taken?

Baricitinib is taken by mouth in tablet form. The tablet should be swallowed whole do not crush or break the tablet.

When should it be taken?

Take this medicine with a full glass of water at the same time each day. It can be taken with or without food.

If you miss a dose: Take a dose as soon as you remember. If it is almost time for your next dose, wait until then and take a regular dose. Do not take extra medicine to make up for a missed dose.

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 alone or with other arthritis medicines including:

- other disease modifying anti rheumatic drugs (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.

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

Baricitinib cannot be used with other biologic DMARDs or targeted synthetic DMARDS (such as tofacitinib).

Are there any side effects?

You might experience side effects with your treatment. Tell your doctor if you notice side effects that you think are caused by this medicine. Many side effects disappear when baricitinib treatment is stopped.

Most common 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. Infections may need treatment and baricitinib may need to be stopped for a while if you develop an infection, so it is important to contact your doctor for advice.
- Gastrointestinal related - nausea (feeling sick), vomiting and diarrhea.
- Blood test abnormalities. 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.

Less common or rare side effects

- Blood clots in the veins of the legs or lungs and arteries are possible in some people taking baricitinib. This can happen more often in patients with an inflammatory condition. Further risk factors including heart disease will be assessed by your doctor.
- Serious infections such as tuberculosis (TB) are seen rarely, and screening for TB is needed before treatment begins.
- Increases in lipid (cholesterol) levels have been noted in some patients when taking baricitinib and will be checked using blood tests.
- Changes in liver function have been seen. It is recommended to have regular liver function tests.
- Baricitinib increases the risk of getting shingles. If you get a painful skin rash with blisters inform your doctor immediately. Vaccination for shingles should be discussed with your rheumatologist before starting treatment.
- People with rheumatoid arthritis are at increased risk of lymphoma and some other cancers. Medicines that change your immune system like baricitinib may increase this risk.
- Skin cancers have been reported in people taking baricitinib and yearly skin checks are recommended.
- Tell your doctor or pharmacist immediately of any of side effects you experience.
- Blood counts: Although abnormalities are usually mild sometimes baricitinib will cause a severe abnormality of your liver or blood.

What precautions are necessary?

Infections

- If you have an active infection of any kind treatment with baricitinib will not be started 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.

Use with other medicines

- Baricitinib can interact with other medicines. You should tell all your doctors about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.

Vaccines

- If you are taking baricitinib you should not be immunised with 'live' vaccines such as:
- MMR (measles, mumps and rubella), varicella vaccines (chicken pox/shingles) OPV (oral polio virus), BCG (Bacillus Calmette Guerin) or Yellow Fever. Talk with your rheumatologist before receiving any vaccines.
- Pneumococcal vaccines and the yearly seasonal flu vaccinations are encouraged.

For more information on vaccination including the COVID-19 vaccination go to the ARA website; https://rheumatology.org.au/ patients, medication information, vaccinations.

Surgery

- If you require surgery for any reason treatment with baricitinib should be stopped one week before surgery. It will be restarted again after the operation at a time agreed by your surgeon and rheumatologist (usually when the wound is healed).

Use in pregnancy and when breastfeeding

- It is important to discuss with you doctor if you are planning a pregnancy while on baricitinib.
- Baricitinib should not be used during pregnancy. Women of childbearing potential should use effective birth control both during treatment and for at least 1 week after final dose of baricitinib.
- Do not breastfeed if you are taking baricitinib as it is uncertain how much of the drug might be excreted in breastmilk.

More detailed information is available at: https://rheumatology.org.au/gps/documents/ARAPrescribersinfoonmedicationsinpregnancy27Apr21_Final.pdf

How to store baricitinib

- Store baricitinib in a cool, dry place, away from direct heat and light (for e.g. not in the bathroom).
- 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

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: 03 9508 3424
Visit our website: www.ARAD.org.au

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.