PATIENT INFORMATION ON
BARICITINIB

[Bear–EE–sit–in–ib]

Brand name: Olumiant®

This information sheet was written by the Australian Rheumatology Association to help you understand the medication that has been prescribed for you. It includes important information about:

- **how you should take your medication**
- **what are the possible side 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. This information sheet is not intended to replace the product information or discussion with your rheumatologist.

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, heart failure or stroke, so that your arthritis treatment can be reviewed.
- 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.
- Patients commencing baricitinib should ensure they have close monitoring of their cardiovascular risk factors, including blood pressure and cholesterol with their local doctor.
- If you are taking baricitinib and plan to become pregnant, you must discuss the timing with your rheumatologist.

TGA BOXED WARNING

Baricitinib should only be used if no suitable treatment alternatives are available in patients:

- With a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors (such as current or past long-time smokers).
- With malignancy risk factors (e.g. current malignancy or history of malignancy).
- Who are 65 years of age and older.

For more information about RHEUMATOID ARTHRITIS and other inflammatory conditions 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 medications 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.

The benefits of continuing baricitinib will be reviewed at each clinic appointment and it is important you advise your treating rheumatologist of any new medical conditions at each visit.

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?

- Baricitinib will only be given if your disease is active and if standard treatments have not worked.
- Baricitinib will only be continued 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 monitor for side effects and to assess if the treatment is working.
- How often you have blood tests will depend on what other medications 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, break or chew the tablet.

When should it be taken?

Take this medication 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 medication to make up for a missed dose.

What is the dosage?

The usual dose for adults with rheumatoid arthritis is 2mg or 4mg taken once a day.

Can other medications be taken with baricitinib?

This medication may be used alone or with other arthritis medications including:

- Other disease modifying anti rheumatic drugs (DMARDs) such as methotrexate.
- Steroid medications such as prednisolone or cortisone injections into the joint.
- Anti-inflammatory medications (NSAIDs) such as naproxen (Naprosyn®) or ibuprofen (Brufen®, Nurofen®).
- Simple pain medications such as paracetamol.
- There may be some instances where these medications may not be right for you, always check with your doctor prior to taking any of these medications.

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 upadacitinib, tofacitinib, etanercept and adalimumab).

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 medication. Many side effects disappear when baricitinib treatment is stopped.

Most common side effects

- The most common side effects reported are mild upper respiratory tract infections (common cold, sinus infections), nausea, cough, and fever. Infections may need treatment and baricitinib may need to be stopped for a while if you develop infection, so it is important to contact your doctor for advice.
- Gastrointestinal related side effects including nausea, vomiting and diarrhoea.
- Blood test abnormalities including mild anaemia. If baricitinib is ceased this usually returns to normal.

Less common or rare side effects

- Blood clots in the veins of the legs, lungs and arteries are possible in some people taking baricitinib. This can happen more often in patients with an inflammatory condition. Other 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 cholesterol levels occur in some patients when taking baricitinib. This will be monitored using blood tests.
- Changes in liver function can occur, it is recommended to have regular liver function tests to monitor this.
- 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. Medications 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.
- It is recommended that patients remain up to date with their age recommended cancer

screens such as mammogram and bowel cancer screening.
- If you experience any side effects, please inform your doctor or pharmacist promptly.

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.

Cardiovascular risk

People with rheumatoid arthritis and other inflammatory conditions have an increased risk of cardiovascular disorders. Recent reports have associated this medication and other JAK inhibitors with an increased risk of heart related events. Ensure your doctor is aware of any pre-existing risk factors (e.g. high blood pressure, high cholesterol, smoking status) so they can be appropriately managed.

Use with other medications

Some medications may not be used with baricitinib as it may change their effectiveness and how well baricitinib may work for you.

Medications that may change how baricitinib works include:

- Antifungals & antibiotics including ketoconazole, itraconazole, posaconazole or voriconazole, clarithromycin, rifampicin and phenytoin.
- Some medications may increase your risk of infection including those used to suppress your immune system including phenytoin, azathioprine, ciclosporin and tacrolimus.
- Other medications may require additional review and monitoring as they may increase the risk of side effects when taking baricitinib including: NSAIDs, opioids and corticosteroids.

This list is not exhaustive. You should inform your doctor and pharmacist of all of the medications you are taking or plan to take. This includes over the counter or herbal/naturopathic medications to see if these affect baricitinib.

Use with alcohol

You may drink alcohol while taking baricitinib. However, if you are also taking methotrexate you should be cautious about how much alcohol you drink.

Vaccines

If you are taking baricitinib you should not be immunised with 'live' vaccines such as:

- MMR (measles, mumps and rubella)
- Varicella (chicken pox/shingles)
- OPV (oral polio virus)
- BCG (bacillus calmette guerin)
- Japanese Encephalitis 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 https://rheumatology.org.au/For-Patients/Adult-Medication-Information/Vaccinations-in-Rheumatology

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.

Use in pregnancy and when breastfeeding

- It is important to inform your 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 the final dose of baricitinib.
- Do not breastfeed if you are taking baricitinib as it is uncertain how much of the medication might be excreted in breastmilk.
- More detailed information is available at https://rheumatology.org.au/For-Patients/Pregnancy-Information

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 medications 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.

Please consider the environment before printing this resource.