Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CUH
Ospidéal Ollscoile Chorcaí
Cork University Hospital

Department of Rheumatology

Baricitinib (Olumiant)

GP Information Sheet

Baricitinib

Baricitinib belongs to a group of medicines called Janus kinase inhibitors. It works by reducing the activity of an enzyme in the body called 'Janus kinase', which is involved in inflammation. By reducing the activity of this enzyme Barictinib helps to reduce pain, stiffness and swelling in the joints, and helps to slow damage to the bone and cartilage in the joints.

Indications

Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Barcitinib may be used as monotherapy or in combination with methotrexate.

Screening Tests

Fbc, Urea, Creatinine, Liver Function Test, Hepatitis screen, Herpes zoster, Quantiferon test, Chest Xray, Fasting lipids

Dosage

The recommended dose of Barcitinib is **4 mg once daily**.
A dose of **2 mg once daily** is appropriate for patients such as those **aged ≥ 75 years** and may be appropriate for patients with a history of **chronic or recurrent infections**. A dose of 2 mg once daily may also be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering.

Precautions

Renal impairment -The recommended dose is 2 mg once daily in patients with creatinine clearance between 30 and 60 mL/min. Barcitinib is not recommended for use in patients with creatinine clearance < 30 mL/min

Hepatic impairment -No dose adjustment is required in patients with mild or moderate hepatic impairment. Barcitinib is not recommended for use in patients with severe hepatic impairment.

Drug Interaction- OAT3 inhibitors can cause elevated levels of barcitinib in blood, the recommended dose is 2 mg once daily in patients taking Organic Anion Transporter 3 (OAT3) inhibitors with a strong inhibition potential, such as probenecid.
Not recommended to be used with other immunosuppressant.
Caution should be used if ibrufen or diclofenec is used in patient taking Barcitinib, however risk of increased exposure is not as significant as with probenecid.

Elderly -May be used in lower dose in patients aged 75 and above.

Possible Side Effects

Infections -increased rate of infections such as upper respiratory tract infections. If an infection develops, Barcitinib therapy should be temporarily interrupted. Barcitinib treatment should not be resumed until the infection resolves.

Tuberculosis -Barcitinib should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of Barcitinib in patients with previously untreated latent TB.

Hematological abnormalities -As described under Lab Monitoring

Viral reactivation -Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies. Barcitinib treatment should be temporarily interrupted until the episode resolves. Patients may be considered to have herpes vaccination prior to start of Barcitinib therapy.

Vaccination -live, attenuated vaccines during, or immediately prior to Barcitinib therapy is not recommended.

Venous Thromboembolism -Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving baricitinib. If clinical features of DVT/PE occur, Barcitinib treatment should be temporarily interrupted and patients should be evaluated promptly.

Lab Monitoring

- FBC and LFTs should be monitored monthly for the first 3 months and every 3 months thereafter

Lymphocyte count (ALC)	
Lab Value (x 10^9/l)	**Recommendation**
≥0.75 cells	Dose should be maintained.
0.5- 0.75 cells	For persistent (2 sequential values in this range on routine testing) decrease in this range, dosing should be interrupted until ALC ≥0.75. When ALC is ≥0.75, restart treatment
<0.5cells	If lab value confirmed by repeat testing within 7 days, dosing should be discontinued.

Neutrophil Count	
Lab Value (10^9/l)	**Recommendation**
≥1 cells	Dose should be maintained.
0.5- 1 cells	For persistent (2 sequential values in this range on routine testing) decreases in this range, dosing should be interrupted until ANC is ≥1cell. When ANC is greater than ≥1, restart treatment
≤0.5 cells	If lab value confirmed by repeat testing within 7 days, dosing should be discontinued.

Haemoglobin Monitoring	
Lab Value (g/dL)	**Recommendation**
Hb ≤ 8g/dL	Treatment should be interrupted and may be restarted once Hb returned above this value

Liver Enzymes	
>2 but < 3 fold rise in AST/ALT from upper limit of reference range	Reduce dose and repeat LFTs
>3 fold rise in AST/ALT from upper limit of reference range	Hold Baricitinib. Repeat LFTs within 2-4 weeks

Pregnancy/ Breast Feeding/ Fertility

Contraindicated during pregnancy. Women of childbearing potential have to use effective contraception during and for at least 1 week after treatment. If a patient becomes pregnant while taking Barcitinib the parents should be informed of the potential risk to the fetus. Should not be used during breast-feeding.
Studies in animals suggest that treatment with baricitinib has the potential to decrease female fertility while on treatment, but there was no effect on male spermatogenesis.

Undesirable Effects

The most commonly reported adverse drug reactions include ; increased LDL cholesterol (33.6%), upper respiratory tract infections (14.7%) and nausea (2.8%).

Contact Details

Dr. S. Harney, Consultant Rheumatologist (secretary):	(021) 4922422
Dr. J. Ryan, Consultant Rheumatologist (secretary):	(021) 4922468
Dr. G. Murphy, Consultant Rheumatologist (secretary):	(021) 4922468
Louise Murphy, Candidate ANP in Rheumatology:	(021) 4920266
Joan Swan, Clinical Nurse Specialist in Rheumatology:	(021) 4922645
Davida Hehir, Clinical Nurse Specialist in Rheumatology:	(021) 4234511

Please consult up to date relevant literature or BNF when prescribing this agent. Please contact the Rheumatology team if you have any other queries regarding the prescribed medication.