

USE OF BARICITINIB IN HOSPITALISED ADULTS WITH COVID-19

INFORMATION FOR PATIENTS, FAMILIES AND CARERS

This information leaflet includes important information about the medicine called baricitinib when used to treat COVID-19.

WHAT IS THE POTENTIAL BENEFIT OF BARICITINIB FOR COVID-19?

Baricitinib belongs to a group of medicines called Janus Kinase (JAK) inhibitors. Baricitinib works by reducing the activity of an enzyme called Janus Kinase, which is involved in inflammation. This enzyme also affects how the immune system works. Baricitinib reduces inflammation and the effects of an over-activated immune system that can occur in severe COVID-19. It probably reduces the risk of dying.

Baricitinib has been approved in Australia to treat some conditions such as rheumatoid arthritis and eczema. The brand name is Olumiant®.

Recent clinical trials have studied how well baricitinib works in COVID-19. Australia's [National COVID-19 Clinical Evidence Taskforce](https://www.nswtag.org.au/covid-19-medicines-resources/) has made recommendations about when baricitinib is most likely to work and not work in the treatment of COVID-19.

WHAT SHOULD BE CONSIDERED WHEN USING BARICITINIB IN COVID-19?

Because the use of baricitinib in COVID-19 is new and baricitinib is not registered to treat COVID-19 in Australia, information about how well it works and how safe it is, is being collected. It is important that patients and their carers understand when and why baricitinib may be useful. Your doctors will provide more information about how well it works and how safe it is in your condition.

Because the use of baricitinib for COVID-19 is new, it is important you provide your formal consent before receiving baricitinib. You can always change your mind about treatment with baricitinib and withdraw consent at any time.

WHAT SHOULD THE DOCTOR KNOW BEFORE BARICITINIB IS USED IN COVID-19?

The doctor should know about:

- any other conditions including low white blood cells, low red blood cells, tuberculosis (including being in contact with someone who has tuberculosis), recurrent infections, HIV or AIDS, hepatitis B or hepatitis C, shingles, diabetes, cancer, high cholesterol, blood clots in the blood vessels of your legs (deep vein thrombosis) or lungs (pulmonary embolism)
- any liver or kidney problems
- previous allergic reactions to any medicine
- all medicines including over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines that you are taking or have recently taken
- the possibility of pregnancy or plans for pregnancy
- recent vaccinations or plans to get vaccinated

WHAT ARE THE SIDE EFFECTS OF BARICITINIB?

All medicines have side effects. Sometimes they are serious, but most of the time they are not, and many of them disappear with time or when treatment is stopped. Medical treatment may be needed with some side effects. Side effects may not be experienced. Some possible side effects that might be experienced during treatment with baricitinib for COVID-19 are shown below. There is a possibility of experiencing other unknown side effects with baricitinib when it is used in people with COVID-19.

Possible side effects of baricitinib	What to do
<ul style="list-style-type: none"> • Nausea (especially at the start of treatment) • Stomach pain • Headache 	Tell the doctor or nurse if these symptoms occur and they can help treat them.
<ul style="list-style-type: none"> • Low white blood cells • Low red blood cells • Effects on the liver 	The doctor will watch for these side effects by doing blood tests.
<ul style="list-style-type: none"> • Infections: <ul style="list-style-type: none"> ○ a cold, sore throat, runny or blocked nose, cough ○ fever, sweating/chills, muscle aches, shortness of breath, warm/red/painful skin sores on your body, burning when you urinate, urinating more often than usual ○ symptoms of shingles such as headache, sensitivity to light, tingling, itching or painful skin rash with blisters. 	Immediately tell the doctor or nurse if you have any of these symptoms
<ul style="list-style-type: none"> • Blood clots in the legs or lungs (painful swollen legs, chest pain or shortness of breath.) 	Immediately tell the doctor or nurse if you have any of these symptoms
<ul style="list-style-type: none"> • Allergic reactions: <ul style="list-style-type: none"> ○ shortness of breath, wheezing, difficulty breathing ○ swelling of the face, lips, tongue or other parts of the body ○ severe skin rash, itching, hives 	Immediately tell the doctor or nurse if these symptoms occur.

Please note: This is not a complete list of all possible side effects. A link to find out more information about the side effects of baricitinib is listed at the end of this information leaflet. Also, the doctor, pharmacist or nurse can provide a more complete list of side effects. Side effects can be reported to the doctor directly and/or to the Therapeutic Goods Administration at www.tga.gov.au/reporting-problems.

HOW IS BARICITINIB GIVEN?

Baricitinib is taken by swallowing the tablet whole with a glass of water. It can be taken with or without food.

Your doctor will decide what dose is right for you and how long you should take it for.

ARE THERE SPECIAL PRECAUTIONS WITH BARICITINIB TREATMENT?

Use with Other Medicines

Baricitinib may interact with some other medicines; sometimes this can be serious. The doctors and other health professionals (such as the pharmacist or nurse) should be informed about all medications normally taken or planned. This includes over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines.

The doctor and pharmacist will check for medicine interactions before baricitinib is started and when it is stopped.

Vaccinations

Because baricitinib can lower the activity of the immune system, infections may occur. The doctors will check for infections and provide advice about future vaccinations for you. Make sure you tell the doctors about any of your recent vaccinations.

Fertility, Pregnancy and Breastfeeding

- It is not recommended that baricitinib is used in pregnant and breastfeeding women who have COVID-19. Consult your doctor or pharmacist for information and advice.
- The effect of baricitinib on fertility is unknown.
- In general, it is recommended women of childbearing potential use adequate contraception for at least one week after the final dose of baricitinib. Consult your doctor for further information.

My notes:

MORE INFORMATION ABOUT BARICITINIB

- Eli Lilly Australia Pty Ltd. Australian Consumer Medicines Information Olumiant® baricitinib 4 mg film-coated tablet blister pack. Therapeutic Goods Administration. Published 23 April 2021 https://search.tga.gov.au/s/search.html?collection=tga-artg&profile=record&meta_i=277917
- National COVID-19 Clinical Evidence Taskforce. Australian Guidelines for the Clinical Care of people with COVID-19. <https://covid19evidence.net.au/#living-guidelines>

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This Information Leaflet is provided to support clinicians if baricitinib is used outside a trial setting.

See <https://www.nswtag.org.au/covid-19-medicines-resources/> for further details.

Page 3 of 3 | Use of baricitinib in hospitalised adults with COVID-19 | Patient Information Leaflet | 8 Oct 2021 | Version 1

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