

USE OF SARILUMAB IN HOSPITALISED ADULTS WITH COVID-19

INFORMATION FOR PATIENTS, FAMILIES AND CARERS

This information leaflet has important information about the medicine called sarilumab when used in the treatment of COVID-19.

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

Sarilumab belongs to a group of medicines called monoclonal antibodies. Monoclonal antibodies are proteins, which specifically recognise and bind to unique proteins in the body to modify the way the immune system works. Sarilumab reduces the effects of an over-activated immune system that can occur in severe COVID-19. It probably reduces the risk of dying.

Sarilumab has been approved in other countries (not Australia) to treat some immune conditions such as arthritis. The brand name is Kevzara™.

Recent clinical trials studying the effectiveness of sarilumab in COVID-19 have been analysed by Australia's [National COVID-19 Clinical Evidence Taskforce](#). This Taskforce makes recommendations about when sarilumab is most likely to be effective in the treatment of COVID-19.

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

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

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

The doctor should know about:

- any other conditions including low white blood cells, low platelets, HIV or AIDS, tuberculosis (including being in close contact with someone who has tuberculosis), recurrent infections, hepatitis B or C, diverticulitis, stomach ulcers, diabetes, heart disease or cancer.
- any liver 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 SARILUMAB?

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 sarilumab are shown below. There is a possibility of experiencing other unknown side effects with sarilumab when it is used in people with COVID-19.

Possible side effects of sarilumab	What to do
<ul style="list-style-type: none"> • Skin reactions around the area where the medicine is injected 	Tell the doctor or nurse if these symptoms occur and they worry you.
<ul style="list-style-type: none"> • New infections <ul style="list-style-type: none"> ○ symptoms of the common cold or flu such as a 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. 	<p>The doctor or nurse will check for any signs of new infection.</p> <p>Immediately tell the doctor or nurse if you have any of these symptoms of infection.</p>
<ul style="list-style-type: none"> • Effects on the liver • Low white blood cells • Low platelets 	<p>The doctor will watch for these side effects by doing blood tests.</p> <p>Tell your doctor or nurse if you have any unexplained bruising or bleeding or are feeling very tired or weak.</p>
<ul style="list-style-type: none"> • Stomach irritation and tears 	Tell the doctor or nurse if stomach pain/tenderness or any vomiting of blood occurs.
<ul style="list-style-type: none"> • Allergic reactions such as skin rash, sudden breathing problems 	Seek medical help immediately if these side effects occur.

Please note: This is not a complete list of all possible side effects. A link to more information on the side effects of sarilumab 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 SARILUMAB GIVEN?

Sarilumab for COVID-19 treatment is given by infusion into a vein (intravenous administration) by a doctor or nurse. The infusion normally takes about one hour and will be given in a hospital setting.

Your doctor will decide what dose is right for you and how many doses you should receive.

ARE THERE SPECIAL PRECAUTIONS WITH SARILUMAB TREATMENT?

Use with Other Medicines

Sarilumab may interact with some other medicines with serious consequences. The doctors and other health professionals (e.g. pharmacist, 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 sarilumab is started and when it is stopped.

Vaccinations

Because sarilumab can depress the immune system, infections may occur. The doctors will monitor 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

- The [National COVID-19 Taskforce](#) provides some guidance about the use of sarilumab in pregnant and breast-feeding women who have COVID-19. Consult your doctor or pharmacist for information and advice.
- The effect of sarilumab on fertility is unknown.
- In general, it is recommended women of childbearing potential should be advised to use adequate contraception for several months after treatment with sarilumab. Consult your doctor for further information as contraceptive medicines may be less effective.

My notes:

MORE INFORMATION ON SARILUMAB

- Sanofi-aventis U.S. Medication Guide Kevzara™ (sarilumab) injection. Published April 2018 https://products.sanofi.us/Kevzara/Kevzara_MedGuide.pdf
- 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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