

USE OF TOCILIZUMAB IN HOSPITALISED ADULTS WITH COVID-19

INFORMATION FOR PATIENTS, FAMILIES AND CARERS

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

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

Tocilizumab 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. Tocilizumab reduces the effects of an over-activated immune system that can occur in severe COVID-19. It probably reduces the risk of dying.

Tocilizumab has been approved in Australia to treat some immune conditions such as arthritis, cytokine release syndrome and giant cell arteritis. The brand name is Actemra®.

Recent clinical trials have studied how well tocilizumab 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 tocilizumab is most likely to work and not work in the treatment of COVID-19.

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

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

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

The doctor should know about:

- any other conditions including HIV or AIDS, tuberculosis, diverticulitis, stomach ulcers, diabetes, cancer, heart problems, raised blood pressure or any nerve disease such as neuropathy
- 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
- any liver or kidney problems
- the possibility of pregnancy or plans for pregnancy

WHAT ARE THE SIDE EFFECTS OF TOCILIZUMAB?

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

Possible side effects of tocilizumab	What to do
<ul style="list-style-type: none"> • Infections • Gastritis e.g. abdominal bloating, pain, vomiting or indigestion • Rash, itch • Headache, dizziness • Mouth ulcers 	Tell the doctor or nurse if these symptoms occur and they can help treat them.
<ul style="list-style-type: none"> • Increased blood pressure • Low white blood cell and platelet count • Effects on the liver, pancreas and lungs 	The doctor will watch for these side effects by doing blood tests.
<ul style="list-style-type: none"> • Gastrointestinal perforation (uncommon) 	Tell the doctor or nurse if abdominal pain/tenderness or any vomiting of blood occurs.
<ul style="list-style-type: none"> • Skin reactions, allergic reactions 	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 tocilizumab 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 TOCILIZUMAB GIVEN?

Tocilizumab 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 TOCILIZUMAB TREATMENT?

Use with Other Medicines

Tocilizumab 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 tocilizumab is started and when it is stopped.

Vaccinations

Because tocilizumab 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.

Fertility, Pregnancy and Breastfeeding

- The [National COVID-19 Clinical Evidence Taskforce](#) provides some guidance about the use of tocilizumab in pregnant and breast-feeding women who have COVID-19. Consult your doctor or pharmacist for information and advice.
- The effect of tocilizumab 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 tocilizumab. Consult your doctor for further information.

My notes:

MORE INFORMATION ABOUT TOCILIZUMAB

- Roche Products Pty Ltd. Australian Consumer Medicines Information Actemra® (tocilizumab) (rch) 200 mg/10 mL injection concentrated vial. Therapeutic Goods Administration. Published April 2020 https://search.tga.gov.au/s/search.html?collection=tga-artg&profile=record&meta_i=149404
- 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 tocilizumab 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 tocilizumab in hospitalised adults with COVID-19 | Patient Information Leaflet | 8 Oct 2021 | Version 1.4

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