

EXPERIMENTAL USE OF TOCILIZUMAB IN HOSPITALISED ADULTS WITH COVID-19

INFORMATION FOR PATIENTS, FAMILIES AND CARERS

The use of medicines to treat COVID-19 infection is largely experimental with information continuing to be gathered.

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

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 has effects on the immune system that may be useful in helping to reduce the effects of severe COVID-19 infection.

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

WHAT IS EXPERIMENTAL USE OF TOCILIZUMAB?

The Therapeutic Goods Administration (TGA) decides which drugs can be registered to treat certain conditions. They base their decision on high quality evidence of effectiveness and safety.

Tocilizumab is not registered to treat COVID-19 infection in Australia because there is not enough evidence on whether it works or is safe in people with COVID-19.

If tocilizumab is used for COVID-19 then this use is considered 'experimental'. It will only be used through participation in a scientific trial or under

certain circumstances where information about its effectiveness and safety can be gathered.

The doctor will explain that the effectiveness or safety of tocilizumab in treating COVID-19 infection is largely unknown. Because tocilizumab is being used experimentally, you must provide your formal consent before receiving tocilizumab. You can 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 INFECTION?

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 	The doctor will monitor for these side effects.
<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 additional 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 drug interactions before tocilizumab is started and when it is stopped.

Vaccinations

Because tocilizumab can depress the immune system, infections may occur. The doctors will monitor for infections and provide advice about future vaccinations.

Fertility, Pregnancy and Breastfeeding

- The effect of tocilizumab on fertility is unknown.
- It is not known if tocilizumab crosses the placenta. There is little information about the possible side effects of tocilizumab on an unborn baby in a pregnant women with COVID-19 infection. Consult the doctor or pharmacist for information and advice.
- Women of childbearing potential should be advised to use adequate contraception for several months after treatment with tocilizumab.
- Tocilizumab may be excreted into breast milk. It is recommended that breastfeeding is stopped during tocilizumab treatment. Consult the doctor or pharmacist for information and advice.

My notes:

ADDITIONAL INFORMATION ON TOCILIZUMAB

- Actemra® (tocilizumab) Consumer Medicine Information: <https://www.nps.org.au/medicine-finder/actemra-concentrate-for-intravenous-infusion>

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