

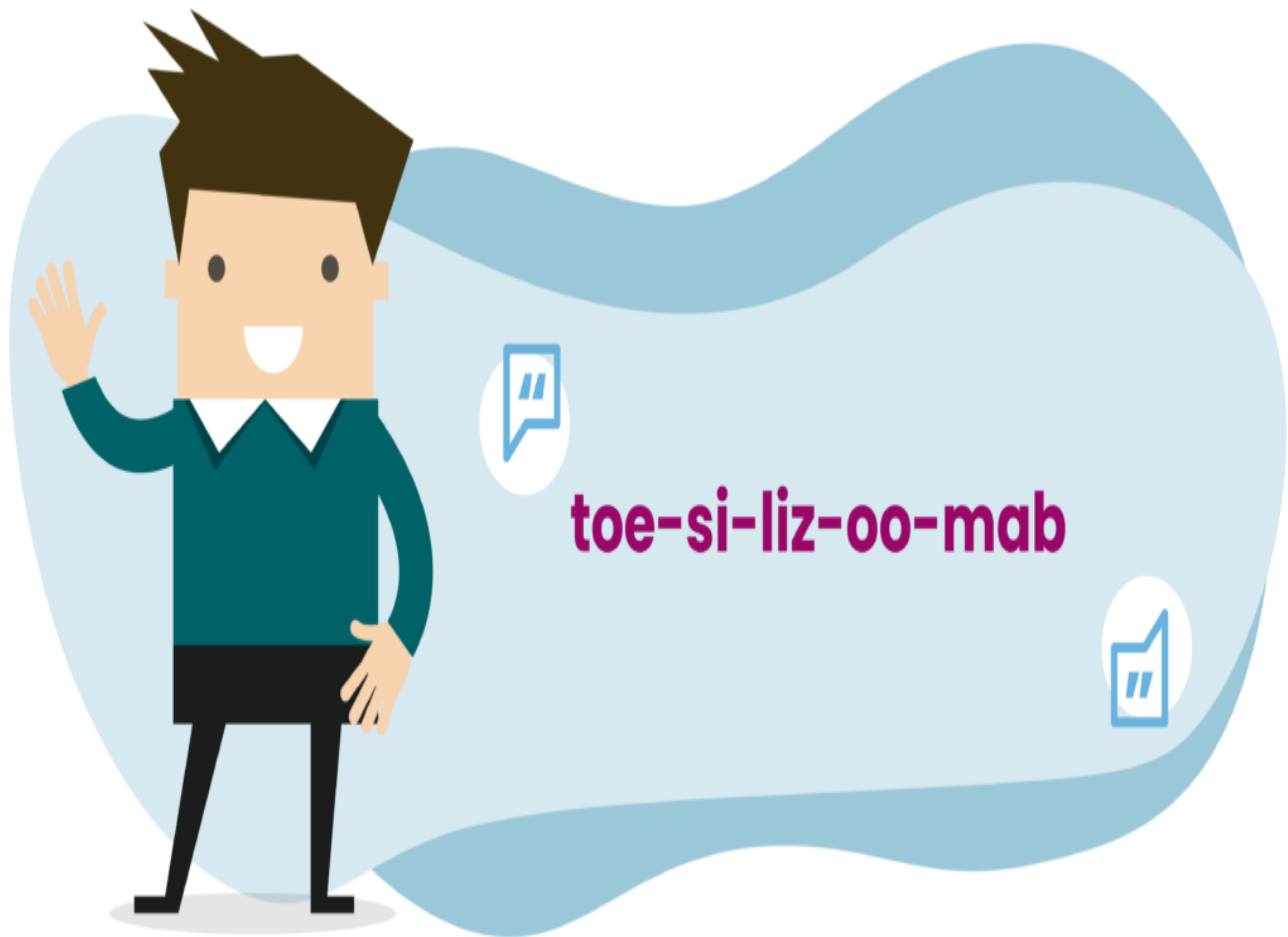


Resource

Tocilizumab

Tocilizumab is a 'biologic' drug. Biologic drugs are often referred to as 'targeted therapies' because they work on specific cells of the immune system. Tocilizumab works on the inflammatory chemical interleukin-6 (IL-6).

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Tocilizumab is manufactured as RoActemra by Roche Products Ltd.

Name of Drug

How the drug is taken

How it works

Blood tests

Tocilizumab (TCZ)	Infusion or subcutaneously		
162mg solution for infusion	In sJIA	Reduces over activity of the immune system by targeting IL6 cells	Yes- every 3 months initially
162mg prefilled syringe for subcutaneous injection	patients weighing less than 30kg: 162mg every 2 weeks		
162mg Prefilled pen for subcutaneous injection	Weighing 30kg or more: 162 mg weekly		

Tocilizumab is currently only available as RoActemra (brand name manufactured by Roche). This is also described as the 'originator' (original version of the drug). In the last few years 'biosimilar preparations' have become available. These are permitted once the patent has expired on the original drug. The biosimilar preparations are copies of the originator although their preparation, how they are produced, for example volume of fluid that contains the drug, may be different). There are currently no biosimilar products available however, these are in development.

Interleukin-6 occurs naturally as part of the immune system. In systemic JIA and polyarticular JIA too much IL-6 is produced and causes symptoms of inflammation in the body (signs of which include pain, heat, swelling and redness in joints). This overproduction needs to be controlled to prevent damage to the joints and other unwanted effects.

Background

Tocilizumab has been recommended by NICE (National Institute for Health and Care Excellence) since 2011 for children and young people and has been developed to control the overproduction of the inflammatory chemical interleukin-6 (IL-6). It is used, for those who have failed previous treatments or been intolerant to them, as a single treatment or in combination with methotrexate. This guidance is also accepted in Scotland.

There has been extensive research into the use of tocilizumab for the treatment of inflammatory arthritis over many years. This research has helped to shape the role for this drug in the treatment of systemic onset Juvenile Idiopathic Arthritis (sJIA) and Polyarticular JIA (pJIA).

How does tocilizumab work?

Tocilizumab is a targeted biologic drug (meaning it works on specific cells) and is licensed for children with:

- Systemic Juvenile Idiopathic Arthritis (sJIA) 1 year and over
- Polyarticular Juvenile Idiopathic Arthritis (pJIA) 2 years and over

The dose is dependent on the child or young person's weight and JIA subtype.

Tocilizumab may take several weeks to be effective (2-12 weeks)

When can tocilizumab be prescribed?

Tocilizumab can only be prescribed for children and young people according to strict guidelines by paediatric and adolescent rheumatologists or specialist nurses who have undertaken non-medical prescribing qualifications. When these guidelines are met, it can be prescribed on its own or together with methotrexate.

Prior to starting treatment with tocilizumab, additional checks are needed to establish if there is any history of tuberculosis (which could be reactivated by this drug); to record vaccinations that have been completed and any other information the prescribing specialist may require.

Whether you are a young person or the parent of a child, it is important that you understand the intended treatment and any possible precautions. Equally important is discussion about the evidence of the benefits of tocilizumab and the need for ongoing research into the longer term potentially unknown facts.

You may be invited to participate in a post marketing registry. This is a database that stores information on the use of biologic drugs and helps to increase the knowledge of these treatments. There is more confidence in the benefit of a treatment when increasing numbers of patients take it for increasing lengths of time without significant side effects. The rheumatology team caring for you will discuss this in more detail.

Prior to tocilizumab being prescribed, the paediatric and adolescent rheumatology doctors may complete regulatory documentation called Blueteq. This is to ensure and monitor eligibility to the medication. Prescribing outside of this guidance requires an Individual Funding Request (IFR). If this is the case, the rheumatology team will discuss this with you.

How is tocilizumab given?

- For systemic onset JIA (sJIA), tocilizumab is given in hospital as an intra-venous infusion once every 2 weeks. For polyarticular JIA (pJIA) the intra-venous infusion is once every 4 weeks
- It can also be given by sub-cutaneous injection which you can be taught to administer at home (see administration guidance in table summary below).
- If being given sub-cutaneously the young person, once old enough, can be encouraged to learn to inject themselves.

The management of this treatment is always discussed in detail at the start. Regular blood monitoring is required; the frequency will depend on the prescribing specialist's advice. Failure to attend for regular blood tests may result in treatment being stopped until a blood test has been undertaken.

The medicines may be supplied from your hospital pharmacy or delivered to you by a homecare company.

What are the possible side effects?

As with any medication, tocilizumab has possible side effects, although it is important to remember that these are only potential side effects and may not occur at all.

- The most common side effect is an infusion reaction and therefore preventative treatment is given beforehand with the steroid hydrocortisone. An infusion reaction might include any of the following symptoms: flushing, headache, nausea or dizziness. Rarely other reactions might be rash, fever, fatigue or a rise or drop in blood pressure. During an infusion, patients are closely monitored, and any possible side effects will be seen very quickly, and the necessary action taken
- Can affect liver therefore careful monitoring of liver function is required
- Tocilizumab can also cause severe infections, such as pneumonia.
- Due to the risk of infection, tattoos and body piercings are not recommended
- Nausea; diarrhoea; headache

Regular blood tests to check any unwanted effects of the treatment are very important

More information on side effects can be found in the patient information on tocilizumab

Remember to report any concerns about possible side effects to the doctors or nurses

Tocilizumab with other medicines

It is important to tell anyone prescribing medications or your pharmacist that you are taking tocilizumab as there may need to be dose adjustments due the effects of other medications. Tocilizumab cannot be prescribed at the same time as another biologic drug, as only one biologic drug is ever prescribed at any one time.

Remember to take care when using any other medications or complementary therapies (even if bought 'over the counter' for colds or flu). Remember to check with a doctor, nurse or pharmacist that they are safe to take with tocilizumab and any other medication taken.

Alert Cards: Your rheumatology nurse should provide you with one of these. This indicates to health professionals that you are on a drug to suppress your immune system and reminds them to be extra-vigilant if you are unwell or having a surgical procedure or invasive dental care, where treatment may need to be temporarily delayed.

Tocilizumab and immunisation/vaccination

Live vaccines [measles, mumps, rubella (MMR), chickenpox, oral polio (NOT injectable polio), BCG, oral typhoid and yellow fever] cannot be given to anyone already taking tocilizumab. If tocilizumab has not yet been started it is important to seek advice on how long a gap to leave after having a live vaccine.

Flu vaccine is now available in two forms, an injection and a nasal spray. Unlike the injection, the nasal spray is a live vaccine. There is limited research evidence around live vaccines in people with a lowered immune system (due to their medication). It is therefore important to discuss with the healthcare team which of these options would be best.

Vaccination of close family members can help to protect someone with a lowered immune system.

Tocilizumab and pregnancy

There is not sufficient research information to give advice that either pregnancy or breastfeeding are safe.

Men or women taking tocilizumab should use reliable contraception during treatment and for 3 months after the last dose before planning to start a family.

Remember to ask your doctor or clinical nurse specialist if you need any further advice.

Tocilizumab and alcohol

Alcohol can be consumed when taking tocilizumab. However, caution may be required when taking other medications alongside this drug, for example methotrexate. Please see our separate articles on other JIA medications.

Tips regarding tocilizumab

- DO NOT ADMINISTER tocilizumab to a child or young person if they have a high temperature or you are concerned they are unwell with an infection – seek medical advice from your GP or rheumatology team.
- Stay safe on tocilizumab by remembering to have regular blood test monitoring as advised by

the consultant or clinical nurse specialist.

- A single syringe or pen device should be removed from the fridge for 15-30 minutes before using, in order to bring it to room temperature as this will help to avoid any stinging at the injection site
- To ease injection site reactions, choose alternate thighs for the injections and by differing the actual site around the mid-thigh region
- An injection site reaction that includes a rash or redness can be eased with a cold compress
- Storage should be in a refrigerator (2°C – 8°C) and the syringes kept in the outer carton in order to protect them from light. Do not freeze

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Tips for travelling with tocilizumab

- Before travelling it is important to keep up to date with vaccinations
- Live vaccines (see above 'Tocilizumab with other medicines') must be avoided. It is important to check whether any required vaccines are 'live' before booking a holiday
- Tocilizumab needs to be kept refrigerated (transport in a cool bag and place in a fridge when you reach your destination). All drugs should be carried in your hand luggage. Your home care delivery company can advise on this and supply smaller sharps bins for travel.
- Your prescribing doctor will have taken details of any vaccinations received or required before starting any biologic drug treatment.
- Your healthcare team can provide you with a letter of authorisation to travel with this drug. Homecare delivery companies also supply letters for travel.

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