

- Are/is taking any other drugs to treat sJIA. This includes oral drugs, such as NSAIDs (e.g. ibuprofen), corticosteroids, MTX and biologic drugs that are injected.
- Have/has an infection
- Have/has had or now has any disease of the liver
- Have/has recently had a vaccine (such as measles, mumps and rubella [MMR] or a travel vaccine) or is scheduled to have one
- Are/is a young woman of childbearing age and may be pregnant or sexually active. Female patients of childbearing potential must use effective contraception during and up to 3 months after treatment. Tocilizumab should not be used during pregnancy unless clearly necessary
- Are/is allergic (hypersensitive) to tocilizumab or any of the other ingredients of tocilizumab.

Summary and contact information

This brochure reviews some of the most important information about tocilizumab.

If you have any questions or problems, always talk to the doctor or nurse.



This information is only for patients
prescribed tocilizumab



RoACTEMRA (tocilizumab) for Systemic Juvenile Idiopathic Arthritis (sJIA)

PATIENT BROCHURE – WHAT YOU SHOULD KNOW

This brochure provides key information to assist patients with sJIA and their parents or guardians to understand the benefits and risks associated with tocilizumab therapy

What you should know about tocilizumab

Finding the right treatment for systemic juvenile idiopathic arthritis (sJIA) is very important and remains a challenge. New treatment options for sJIA mean more patients are likely to find the relief they need. All drugs carry both benefits and potential risks to our health and it is important that you fully understand these. Finding the balance between the two will lead you to a treatment that works best for you/your child. RoActemra, which contains the active substance tocilizumab, might be that treatment.

The doctor has prescribed you/your child tocilizumab. This brochure will answer some questions you/your child may have about the side effects and potential risks of tocilizumab. You/your child will also find important information in the Patient Information Leaflet that comes with tocilizumab. This brochure and the Patient Information Leaflet do not take the place of speaking to the doctor or nurse.

Tocilizumab is indicated for the treatment of active sJIA in patients 2 years of age and older, who have responded inadequately to previous therapy with non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids. Tocilizumab can be given alone (in case of intolerance to methotrexate [MTX] or where treatment with MTX is inappropriate) or in combination with MTX.

Tocilizumab has worked well in patients who were not helped by other drugs, such as corticosteroids or NSAIDs.



What you should know about sJIA and tocilizumab

What causes sJIA?

The exact cause of sJIA is unclear. Our immune system has developed to protect us from foreign substances like germs, but in sJIA, the immune system doesn't behave properly and attacks the body as well. Unlike the other forms of JIA (such as oligoarticular and polyarticular), the immune system not only attacks the joints, but often causes inflammation of internal organs, leading to the symptoms people have with sJIA. These include joint and muscle pain, fever, skin rash and impaired physical function.

What is Interleukin-6?

Interleukin-6 (IL-6) is a protein that is made by the immune system. The body uses IL-6 to manage infections and other processes. IL-6 also plays a major role in the signs and symptoms of sJIA. Some people with sJIA have too much IL-6.

What is tocilizumab?

Tocilizumab is a biologic drug (a type of therapy made from living cells) that blocks the actions of IL-6 in the body. It is used in children and young adults to treat sJIA.

How has tocilizumab been studied?

Tocilizumab has been studied in children and young adults with sJIA. It has been studied with and without MTX.

How is tocilizumab used?

Tocilizumab can be given alone or in combination with MTX. Tocilizumab has not been studied and should not be used with other biologic drugs for sJIA that are injected because of the possibility of increased risk of infection.

How is tocilizumab given?

A doctor or nurse will give tocilizumab to you/your child. It is given by an intravenous (IV) infusion with a needle, most likely in the arm. It will take approximately one hour for one complete dose of tocilizumab to be given.

The dose of tocilizumab is based on your/your child's weight, so each patient's dose may be different and may change through the treatment course. Tocilizumab is given every two weeks. The doctor may also change the dose during treatment based on results from blood tests.

It is important that you/your child does not miss their scheduled dose of tocilizumab. If this happens, contact the doctor. He or she will tell you when you/your child should get their next dose.

Your doctor or nurse will test your/your child's blood to help guide their treatment. Here are some things they may look at:

- **Platelets:** Some people taking tocilizumab had a drop in the number of platelets in their blood. The body uses platelets to help stop bleeding. In clinical trials, the drop in platelets wasn't associated with any bleeding events
- **White blood cells:** Having enough white blood cells is important to help our bodies fight infections. Tocilizumab works on the immune system and can cause the number of white blood cells to drop. For this reason, the doctor will test to make sure you/your child has enough white blood cells and monitor for signs and symptoms of infection
- **Liver function tests:** The doctor may test levels of liver enzymes and bilirubin in your/your child's blood. Some people who have taken tocilizumab have had a rise in liver enzymes. This did not result in injury to the liver. Rises in liver enzymes were seen more often when drugs that could be harmful to the liver were used with tocilizumab. If your/your child's blood test shows a rise in liver enzymes, the doctor should take care of this right away. The doctor may decide to change the dose of tocilizumab or the other medication you/your child may be taking, or potentially stop their treatment with tocilizumab altogether
- **Cholesterol:** Some people who have taken tocilizumab have had a rise in cholesterol. If your/your child's blood test shows an increase in cholesterol, the doctor may prescribe a cholesterol-lowering drug
- **Macrophage activation syndrome (MAS):** Patients with sJIA may develop a condition called macrophage (a type of white blood cell) activation syndrome (MAS), which can be life-threatening. Tocilizumab has not been studied in patients during an episode of active MAS. The doctor will monitor for signs of this syndrome.
- **Vaccination:** Tocilizumab is a drug that affects the immune system and may lower the body's ability to fight infection. Immunisation with live or live-attenuated vaccines (which contain very small amounts of the actual or weakened germs), such as those for measles, mumps or rubella (constituents of MMR vaccine) should not be given during treatment with tocilizumab. Patients with sJIA should be brought up to date with all immunisations before starting tocilizumab.

What are the most common side effects of tocilizumab?

The most common side effects of tocilizumab are upper respiratory tract infections, with typical symptoms such as cough, blocked nose, runny nose, sore throat and headache.

Possible serious side effects include serious infections and allergic (hypersensitivity) reactions, that may, in a small number of cases, be life-threatening. If you notice any of the following signs of:

Allergic reactions during or after infusion, tell the doctor **immediately**.

- Difficulty with breathing or light-headedness
- Rash, itching, hives, swelling of the lips

Infections, tell the doctor **as soon as possible**.

- Fever and chills
- Mouth or skin blisters
- Stomach ache
- Persistent headaches

Other side effects include:

- Skin infections sometimes with fever and chills, pneumonia (lung infection), oral herpes simplex (cold sores), herpes zoster (shingles)
- Mouth ulcers, gastritis (stomach inflammation)
- Rash, pruritus (itchy skin), urticaria (hives)
- Headache, dizziness
- Increased hepatic transaminases (liver enzymes) and bilirubin, indicating changes in the way the liver works
- Hypertension (high blood pressure)
- Leukopenia, neutropenia which can mean a reduction in the infection fighting cells in the blood
- High cholesterol and/or triglycerides (high blood fat)
- Conjunctivitis (eye infection)
- Abdominal pain
- Weight gain
- Fluid retention (oedema) in lower legs
- Cough, shortness of breath

Speak to the doctor if you have any questions about this information.

What are the serious side effects of tocilizumab?

Infections: Tocilizumab is a drug that affects the immune system. The immune system is important because it helps to fight infections. The ability to fight infections may be lowered with tocilizumab. In the sJIA clinical trials serious infections were similar to those seen in RA patients with the addition of varicella (chicken pox) and otitis media (ear infections). Some infections may potentially become serious while on tocilizumab. These may require hospital treatment or may even lead to death so it is very important to report any signs of infection to the doctor right away.

Infusion reactions: Most infusion reactions happen during infusion or within 24 hours after infusion. Angioedema (swelling of the skin) has been seen during infusion. Side effects seen within 24 hours of infusion may include (but were not limited to):

- Rash
- Diarrhoea
- Arthralgia (joint pain)
- Urticaria (hives)
- Epigastric discomfort (tummy ache, bloated feeling)
- Headache

During the infusion, you/your child will be monitored closely for any signs of a hypersensitivity or anaphylactic reaction. If you/your child experiences a hypersensitivity or anaphylactic reaction, the infusion should immediately be stopped and appropriate treatment given by the doctor. If an anaphylactic reaction or other serious hypersensitivity/serious infusion related reaction occurs, tocilizumab should be permanently discontinued.

Malignancies: Many drugs used to suppress the immune system, such as tocilizumab, may be associated with an increased risk of cancer. Not enough is known about the effect of tocilizumab on cancer. Long-term safety studies are ongoing.

Tell the doctor about any side effects you/your child may have. The side effects listed in this brochure are not all of the possible side effects with tocilizumab. A full list of side effects is available in the patient information leaflet that should be given to you by the doctor or nurse prior to treatment. Always discuss any questions that you may have with the doctor.

Adverse events should be reported. Reporting forms and information can be found at www.medicinesauthority.gov.mt/pub/adr.doc. Adverse events should also be reported to Roche Products Limited. Please contact UK Drug Safety Centre on: +44 1707 367554.





Before starting tocilizumab, tell the doctor if you/your child:

- Have/has an infection (fever, cough, headache, feeling unwell, or open skin sores) or is being treated for an infection
- Get/s a lot of infections
- Have/has diabetes or other conditions that increase the chance for infections
- Have/has tuberculosis (TB), or has been in close contact with someone who has had TB. Your doctor should test you or your child for TB before starting tocilizumab
- Have/has recently had a vaccination (immunisation) or is due to have a vaccination.
- Have/has cancer or a history of cancer
- Have/has cardiovascular risk factors such as raised blood pressure and raised cholesterol levels
- Are/is allergic (hypersensitive) to tocilizumab or any of the other ingredients of tocilizumab
- Have/has a history of macrophage activation syndrome (MAS).
- Could be pregnant
- Are/is on a sodium controlled diet
- Have/has had or now has viral hepatitis or any disease of the liver

Tocilizumab may not be right for you/your child. At each visit, tell your doctor or nurse if you/your child:

- Are/is taking other medicines. Tell your doctor or nurse about all the medicines you/your child takes. This includes prescription and non-prescription drugs, vitamins and herbal supplements. You/your child can take other drugs if your doctor has said that it is okay to take them while also taking tocilizumab. Tocilizumab may interact with some medications. This may affect the dose you/your child needs of that drug. Tell the doctor if you/your child is taking medicines that contain:
 - statins, used to reduce cholesterol levels
 - calcium channel blockers (e.g. amlodipine), used to treat raised blood pressure
 - theophylline, used to treat asthma
 - phenytoin, used to treat convulsions

