Tyenne®
tocilizumab

Important Safety Information for Patients

This brochure provides key information to help patients and their caregivers understand the use of tocilizumab therapy

This educational material is provided by Fresenius Kabi and is mandatory as a condition of the marketing authorisation of tocilizumab in order to minimise important selected risks.

For more information on **tocilizumab**, please see the Patient Information Leaflet (PIL) and the Patient Alert Card provided to you by your healthcare professional. This information is also available at www.medicines.org.uk

Patients should report any device issues to their homecare company to arrange for a replacement and the return of the device. Devices should be returned, and not disposed of in a sharps bin if faulty.

Patients should also report any adverse events associated with a device fault.

If you have any further questions, please ask your doctor, nurse or pharmacist.

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How is tocilizumab given?

Tocilizumab is administered either as an intravenous (into a vein) (IV) infusion with a needle or subcutaneous (under the skin) (SC) injection using a pre-filled syringe (PFS) or pre-filled pen.

Tocilizumab can be prescribed by doctors to appropriate patients for the treatment of:

- Rheumatoid Arthritis (RA)
- Giant Cell Arteritis (GCA)
- Systemic Juvenile Idiopathic Arthritis (sJIA)
- Juvenile Idiopathic Polyarthritis (also known as polyarticular Juvenile Idiopathic Arthritis; pJIA)
- Chimeric Antigen Receptor (CAR) T-cell induced severe or life-threatening Cytokine Release Syndrome (CRS)
- Coronavirus disease-2019 (COVID-19) if patients are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation

Refer to the Patient Information Leaflet for further information.

Medicines are sometimes prescribed for purposes other than those listed. Do not use tocilizumab for a condition for which it was not prescribed.

Before starting treatment with tocilizumab

Before starting tocilizumab, tell the doctor or nurse if you:

- Have signs of an infection (such as a fever, cough or headache, have a skin infection with open sores – e.g. chicken pox or shingles), are being treated for an infection, or get frequent infections. Have diabetes or other conditions that increase the chance for infections
- Have tuberculosis (TB) or have been in close contact with someone who has had TB. Your doctor should test you for TB before starting tocilizumab
- Have had intestinal ulcers or diverticulitis (inflammation in parts of your large intestine)
- Have/had liver disease, viral hepatitis
- Have recently had a vaccination (immunisation), such as that for measles, mumps, rubella (MMR), or are scheduled to have one. You should be brought up to date with all immunisations before starting tocilizumab. Certain types of vaccines should not be administered while on tocilizumab
- Have cancer. Discuss with your doctor or nurse if you should receive tocilizumab
- Have heart or circulatory disease such as high blood pressure or high cholesterol
- Have had any allergic reactions to previous medications, including tocilizumab
- Have had or now have impaired lung function (e.g., interstitial lung disease, where inflammation and scarring in the lungs make it difficult to get enough oxygen)

In addition, for patients with sJIA, also tell the doctor or nurse if you:

- Are taking any other medications to treat sJIA – this includes oral medications, such as NSAIDs (e.g., ibuprofen), corticosteroids, methotrexate and biologic drugs
- Have a history of macrophage activation syndrome (MAS)

During treatment with tocilizumab

What tests will be done when receiving treatment with tocilizumab?

At each visit to see your doctor or nurse, they may test your blood to help guide your treatment. Here are some things they may look at:

Neutrophils

Having enough neutrophils is important to help our bodies fight infections. Tocilizumab works on the immune system and can cause the number of neutrophils, a form of white blood cells, to drop. For this reason, your doctor may test to make sure you have enough neutrophils and monitor for signs and symptoms of infection.

Platelets

Platelets are small blood components that help stop bleeding by forming clots. Some people taking tocilizumab have had a drop in the number of platelets in their blood. In clinical trials, the drop in platelets was not associated with any serious bleeding.

Liver enzymes

Liver enzymes are proteins produced by your liver which may be released into your blood, sometimes indicating liver damage or disease. Some people who have taken tocilizumab have had a rise in liver enzymes, which could be a sign of liver damage. Rises in liver enzymes were seen more often when medications that could be harmful to the liver were used with tocilizumab.

If you have a rise in liver enzymes, your doctor should take care of this right away. Your doctor may decide to change your dose of tocilizumab, or of other medication, or potentially stop treatment with tocilizumab altogether.

Cholesterol

Some people who have taken tocilizumab have had a rise in blood cholesterol, which is a type of lipid (fat). If you have an increase in cholesterol, your doctor may prescribe a cholesterol-lowering medication.

Can patients have vaccinations during treatment with tocilizumab?

Tocilizumab is a medication 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 germ or weakened germs, such as the MMR vaccine), should not be given during treatment with tocilizumab.

What are the potential serious side effects of tocilizumab?

Infections

Tocilizumab is a medication that affects your immune system. Your immune system is important because it helps you fight infections. Your ability to fight infections may be lowered with tocilizumab. Some infections may become very serious while on tocilizumab. Serious infections may require immediate treatment and hospitalisation.

It is very important to report any signs of infection to your doctor or nurse right away.

Seek immediate medical attention if you develop signs/symptoms of infection such as:

- Fever and chills
- Wheezing
- Persistent cough
- Weight loss
- Stomach ache
- Red or swollen skin or mouth blisters, skin tears or wounds
- Severe weakness or tiredness
- Throat pain or soreness

Abdominal pain

Patients taking tocilizumab have on rare occasions experienced serious side effects in their stomach and intestines. Symptoms may include fever and persistent abdominal pain with change in bowel habits. **Seek immediate medical attention** if you develop stomach pain or colic, or notice blood in your stool.

Hepatotoxicity

Tocilizumab treatment can often cause an increase in a specific set of blood laboratory tests called 'liver enzyme' tests which are used to measure the function of your liver. Changes in these liver enzyme blood tests will be monitored regularly while you are receiving tocilizumab.

On rare occasions, patients have experienced serious life-threatening liver problems, some of which have required liver transplant. Rare side effects, which may affect up to 1 in every 1,000 patients receiving tocilizumab, include inflammation of the liver (hepatitis) and jaundice (yellowing of the skin). Very rarely (affecting 1 in every 10,000 patients receiving tocilizumab) patients can experience liver failure.

- **Tell your doctor immediately** if you notice a yellowing of the skin and eyes, have dark brown coloured urine, pain or swelling in the upper right side of the stomach area or you feel very tired and confused
- Tell your doctor if you have liver disease before you receive tocilizumab

If you experience any of the above side effects, **do not take the next dose until you have informed your doctor** AND your doctor has told you to take the next dose.

Malignancies

Medicines which act on the immune system, like tocilizumab, may increase the risk of malignancy. Your doctor will help you decide whether tocilizumab treatment is right for you.

Side effects in children and adolescents with sJIA or pJIA

Side effects in children and adolescents with sJIA or pJIA are generally similar to those in adults. Some side effects are seen more often in children and adolescents: inflamed nose and throat, headache, feeling sick (nausea) and lower white blood cell counts.

Children and adolescents

Tocilizumab pre-filled pen should not be used in children under 12 years of age. Tocilizumab must not be given to children with sJIA weighing less than 10 kg. If a child has a history of macrophage activation syndrome (activation and uncontrolled proliferation of specific blood cells), tell your doctor. Your doctor will have to decide if they can still be given tocilizumab.

Summary and contact information

This patient brochure reviews some of the most important information about tocilizumab. Tell your doctor, nurse or pharmacist about any side effect you experience, bothers you or that does not go away. These side effects listed in this brochure are not all of the possible side effects that you could experience with tocilizumab. Ask your doctor, nurse or pharmacist for more information. Talk to your doctor, nurse or pharmacist if you have any questions or problems.

Reporting of side effects

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet.

You can also report side effects directly via: Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store.

You should also report side effects to Fresenius Kabi by emailing pharmacovigilance.gb@fresenius-kabi.com or calling + 44 (0) 1928 533 575.

By reporting side effects you can help provide more information on the safety of this medicine.

Detailed information on this medicine is available at www.medicines.org.uk or products.mhra.gov.uk

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