

For use in Ireland



# Avtozma<sup>®</sup>▼ (tocilizumab) Patient Brochure

---

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

---

This educational material is provided by Celltrion Healthcare and is mandatory as a condition of the marketing authorisation of Avtozma in order to minimise important selected risks.

This brochure contains important safety information that you need to be aware of before and during treatment with Avtozma. For more information on Avtozma, please see the Patient Information Leaflet (PIL) that comes with the medication and the Patient Alert Card provided to you by your healthcare professional. This information is also available at [www.hpra.ie](http://www.hpra.ie) and [www.medicines.ie](http://www.medicines.ie).

The information that you receive in these documents complements the information that you will receive from your doctor, nurse, or pharmacist. If you have any further questions, please ask your doctor, nurse or pharmacist.

## How is Avtozma given?

Avtozma 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 or pre-filled pen.

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

- Rheumatoid Arthritis (RA) (IV or SC)
- Giant Cell Arteritis (GCA) (SC)
- Polyarticular Juvenile Idiopathic Arthritis (pJIA) (IV or SC)
- Systemic Juvenile Idiopathic Arthritis (sJIA) (IV or SC)
- Chimeric Antigen Receptor (CAR) T cell-induced severe or life-threatening Cytokine Release Syndrome (CRS) (IV)
- Coronavirus disease 2019 (COVID-19) in hospitalised adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation (IV)

Refer to the Patient Information Leaflet for further information.

Do not use Avtozma for a condition for which it was not prescribed.

Avtozma pre-filled pen is not recommended for use in children under 12 years of age.

## Before starting treatment with Avtozma

### Before starting Avtozma, tell the doctor or nurse if you you/your child:

- Have signs of an infection (such as a fever, cough or headache), have a skin infection with open sores (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 had tuberculosis (TB) or have been in close contact with someone who has had TB. Your doctor should test you for TB before starting Avtozma
- Have had intestinal ulcers, diverticulitis (inflammation in parts of your large intestine)
- Have/had liver disease or viral hepatitis
- Have recently had a vaccination (immunisation), such as that for measles, mumps, rubella (MMR), or are scheduled to have one. Certain types of vaccines should not be administered while on Avtozma
- Have cancer. Discuss with your doctor or nurse if you should receive Avtozma
- Have heart or circulatory disease such as high blood pressure or high cholesterol
- Have had any allergic reactions to previous medications, including Avtozma
- Have had or now have impaired lung function
- Have moderate to severe kidney function problems
- Have persistent headaches
- Are taking any other medications. This includes oral medications, such as NSAIDs (e.g. ibuprofen), corticosteroids, methotrexate (MTX) and biologic drugs.



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

- Have a history of macrophage activation syndrome (activation and uncontrolled proliferation of specific blood cells).  
Your doctor will have to decide if they can still be given Avtozma.

Avtozma must not be given to children with sJIA weighing less than 10 kg.

## During treatment with Avtozma

### What tests will be done when receiving treatment with Avtozma?

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. Avtozma 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.

If you/your child have a drop in neutrophils the doctor may decide to interrupt treatment, or potentially stop treatment with Avtozma altogether.

#### **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.

If you/your child have a drop in platelets the doctor may decide to interrupt treatment, or potentially stop treatment with Avtozma altogether.

### **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 Avtozma.

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 Avtozma, or of other medication, or potentially stop treatment with Avtozma altogether.

### **Cholesterol**

Some people who have taken Avtozma 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 Avtozma?**

Avtozma 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 Avtozma.

Patients should be brought up to date with all vaccinations before starting Avtozma.

Please consult your doctor for further information regarding vaccination and Avtozma treatment.



## What are the potential serious side effects of Avtozma?

### Allergic reactions

Avtozma may cause allergic reactions during or after injection. If you experience chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips, tongue or face, or itching, hives or rash, seek medical attention immediately. This is potentially a medical emergency.

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

### Infections

Avtozma 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 Avtozma. Some infections may become very serious while on Avtozma. Serious infections may require immediate treatment and hospitalisation and in some cases may lead to death.

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

Tell your doctor immediately if you or your child develop any signs/symptoms suggestive of a tuberculosis infection (such as persistent cough, wasting/weight loss, listlessness, mild fever) during or after treatment with Avtozma.

## Abdominal pain

Patients taking Avtozma have on rare occasions experienced serious side effects in their stomach and intestines.

Symptoms may include fever and persistent abdominal (stomach) pain with change in bowel habits. **Seek immediate medical attention** if you develop stomach pain or colic, or notice blood in your stool.

## Hepatotoxicity

Avtozma 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. Before you use Avtozma, your doctor may do blood tests to measure your liver function. Changes in these liver enzyme blood tests will be monitored regularly while you are receiving Avtozma.

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 Avtozma, include inflammation of the liver (hepatitis) and jaundice (yellowing of the skin). Very rarely (affecting up to 1 in every 10,000 patients receiving Avtozma) 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 Avtozma

## Malignancies

Medicines which act on the immune system, like Avtozma, may increase the risk of malignancy. Your doctor will help you decide whether Avtozma 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.



## Summary and contact information

This patient brochure reviews some of the most important information about Avtozma. The side effects listed in this brochure are not all of the possible side effects that you could experience with Avtozma.

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 to HPRA Pharmacovigilance via [www.hpra.ie](http://www.hpra.ie). You should also report side effects to Celltrion by emailing [medinfoie@celltrionhc.com](mailto:medinfoie@celltrionhc.com) or calling (01) 564 5074. By reporting side effects you can help provide more information on the safety of this medicine.

