Reporting of side effects

For full information on all possible side effects please see the Avtozma Package Leaflet that comes with your medication (and can also be found on www.medicines.ie).

▼ 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.

You should also report side effects to Celltrion by emailing medinfoie@celltrionhc.com or calling (01) 564 5074.

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

Dates of Avtozma treatment: *

Start:

Route of administration: ☐ IV ☐ SC

***Please make sure you also have a list of all your other medicines with you at any visit to a healthcare professional**

Patient's name:

Doctor's name:

Doctor's phone number:

Avtozma™ ▼ tocilizumab

HEALTHCARE CELLTRION

IE-AVT-PV-0925-03 September 2025 Ver.1.0
HPRA Approved: November 2025

For use in Ireland

Avtozma®▼(tocilizumab) Patient Alert Card

This card is for both paediatric and adult patients. Use accordingly.

This patient alert card contains important safety information that patients or parents/guardians of patients need to know before, during and after you or your child's treatment with Avtozma. Avtozma may be administered as an intravenous (IV) infusion or a subcutaneous (SC) injection.

- Show this card to ANY healthcare professional involved in your/your child's care
- Read the Avtozma Package Leaflet that comes with your medicine and the Avtozma Patient Brochure (provided by your doctor) for more information

General

Tocilizumab may be given as an injection into the vein (intravenous, IV) or under the skin (subcutaneous, SC) depending on what you are being treated for.

- As a Rheumatoid arthritis (**RA**), polyarticular Juvenile Idiopathic Arthritis (**pJIA**), or systemic Juvenile Idiopathic Arthritis (**sJIA**) patient, your treatment may be administered as an IV infusion or SC injection
- As a Giant Cell Arteritis (**GCA**) patient, your treatment will be by SC injection only
- As a COVID-19 or cytokine release syndrome (**CRS**) patient, your treatment will be by IV infusion only.

Infections

Avtozma can reduce your body's ability to respond to infections and may make an existing infection worse or increase the chance of getting a new infection. You should not receive Avtozma if you have an active serious infection. In addition, some previous infections may reappear with use of Avtozma.

Infections can become serious if not treated so tell your/your child's doctor immediately if signs/symptoms of infection develop such as:

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

Patients and parents/ guardians should…

- Tell your doctor if you/your child have recently been vaccinated, or if a vaccination is planned, and talk about any vaccines you may need before starting treatment with Avtozma
- Seek medical advice if any signs/symptoms (such as persistent cough, weight loss, listlessness, mild fever) suggestive of a tuberculosis (TB) infection occur during or after treatment with Avtozma. You should have been screened and found to have no active TB prior to treatment with Avtozma
- Younger children may be less able to communicate their symptoms therefore parents/guardians of younger patients should contact their healthcare professional immediately if their child is unwell for no apparent reason
- Seek guidance from your healthcare professional about whether you should delay your next treatment if you have an infection of any kind (even a head cold) at the time of your scheduled treatment

Complication of diverticulitis

Patient using Avtozma may develop complications of diverticulitis, which can become serious if not treated.

- **Seek immediate medical attention** if you/your child develop fever and persistent stomach pain or colic with change in bowel habits, or notice blood in the stool
- Inform your doctor if you/your child have or have had intestinal ulceration or diverticulitis (inflammation in parts of your large intestine)

Hepatotoxicity

Tell your doctor if you/your child has liver disease. Avtozma treatment can often cause an increase in a specific set of blood laboratory tests called 'liver enzymes' which are used to measure the function of your liver. Your doctor may check your liver enzyme blood tests before starting Avtozma, and you will be monitored regularly for changes in these tests during your treatment.

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 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

Keep this card for at least 3 months after the last Avtozma dose, since side effects could occur for some time after the last dose of Avtozma.

If you/your child experience any untoward effects and have been treated with Avtozma in the past, contact your healthcare professional for advice.