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 and your child's treatment with Avtozma. Avtozma treatment may be administered as an intravenous (IV) infusion or subcutaneous (SC) injection.

- Show this card to ANY healthcare professional involved in your care
- Read the Avtozma Product Information Leaflet that comes with your medicine and Avtozma Patient Brochure for more information

General

As a Rheumatoid arthritis (RA), polyarticular or systemic juvenile idiopathic arthritis (pJIA/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 patient, your treatment will be IV infusion only.

Infections

Avtozma may make an existing infection worse or increase the chance of getting infections. You should not receive Avtozma if you have an active serious infection. In addition, some previous infections may reappear with use of Avtozma.

Patients and parents/ guardians of sJIA or pJIA patient should

- Seek medical advice if any signs/symptoms (such as persistent cough, wasting/weight loss, low-grade 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
- Talk to your healthcare professional about any vaccinations you may need before you start treatment with Avtozma
- Tell your doctor immediately if you experience signs or symptoms of an infection. Some infections might become very serious and may require immediate treatment and hospitalisation
- 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
- Younger children with pJIA/sJIA may be less able to communicate their symptoms therefore parents/guardians of pJIA or sJIA patients should contact their healthcare professional immediately if their child is unwell for no apparent reason

Complication of diverticulitis

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

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

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. 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 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

Keep this card for at least 3 months after the last Avtozma dose, since side effects could occur for some time after you last dose of Avtozma. If you experience any untoward effects and have been treated with Avtozma in the past, contact healthcare professional for advice.

Reporting of side effects

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 **Malta Medicines Authority** ADR reporting form which is available online at: http://www.medicinesauthority.gov.mt/adrportal, and by post or email to:

Post: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.

Email: postlicensing.medicinesauthority@gov.mt.

You should also report side effects to:

Mint Health Ltd, 3/4 Cantrija Complex, Triq it-Targa,Il-Maghtab, Naxxar NXR6613 Malta

Telephone: +356 2093 9800

Email: pharmacovigilancemt@mint.com.mt.

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/Parent's/Guardian's name:

Doctor's name:

Doctor's phone number: