

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-Magħtab, 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.

Patient Card

Avtozma[®] ▼
(tocilizumab)

This patient card contains important safety information that you need to be aware before, during and after treatment with Avtozma. Show this card to ANY healthcare professional involved in your/your child's care. Must read the Avtozma Product Information Leaflet that comes with your/your child's medicine, as it contains important information, including instructions for use.

Dates of Avtozma treatment:*

Start:

Most recent:

Route of administration: ☐ IV ☐ SC

Next scheduled administration:

**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:

Approval date by MMA: July 2026

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/your child 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 - Wheezing
 - Persistent cough - Red or swollen skin or mouth blisters, skin tears or wounds
 - Weight loss - Severe weakness or tiredness
 - Throat pain or soreness - Stomach ache
- Before starting treatment with Avtozma, tell the doctor if you/your child have recently been vaccinated and talk to the doctor about any vaccinations that you/your child may need. Patients should be up-to-date with all their vaccinations before they start treatment with Avtozma.
- Seek immediate medical advice if you/your child develop any signs/symptoms suggestive of a tuberculosis (TB) infection (such as persistent cough, wasting/weight loss, listlessness, mild fever) during or after treatment with Avtozma. You/your child 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/caregivers of younger children should contact the doctor immediately if their child is unwell for no apparent reason
- Seek guidance from your/your child's doctor about whether the next treatment should be delayed if you/your child have an infection of any kind (even a head cold) at the time of your scheduled treatment

Complication of diverticulitis

You/your child may develop complications of diverticulitis, which can become serious if not treated.

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

Hepatotoxicity

If you/your child has liver disease, tell your doctor. Before you/your child uses Avtozma, your doctor may do a blood test to measure your/your child's liver function. Increases in a specific set of blood laboratory tests called liver enzymes have been seen commonly in the blood of patients with Avtozma. You/your child will be monitored closely for changes in liver enzymes in the blood during treatment with Avtozma and appropriate action taken by your doctor.

Inflammation of the liver (hepatitis) and jaundice have been reported rarely with Avtozma (rare side effects may affect up to 1 in every 1,000 users). Cases of liver failure, some of which resulted in liver transplantation, have been reported very rarely with Avtozma (very rare side effects may affect up to 1 in every 10,000 users).

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. You/your child might not have any symptoms in which case any increase in liver enzymes will be detected by blood tests.