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Avtozma (*tocilizumab*)

An overview of Avtozma and why it is authorised in the EU

What is Avtozma and what is it used for?

Avtozma is a medicine used to treat:

- adults with severe rheumatoid arthritis that is getting worse, who have not been previously treated with a medicine called methotrexate;
- adults with moderate to severe active rheumatoid arthritis in whom previous treatments with disease modifying anti-rheumatic drugs (DMARDs), such as methotrexate, or medicines known as tumour necrosis factor (TNF) blockers, have not worked well enough or were not tolerated;
- children from 2 years of age with active systemic juvenile idiopathic arthritis in whom other treatments (anti-inflammatory medicines called NSAIDs and corticosteroids) have not worked well enough;
- children from 1 year of age with juvenile idiopathic polyarthritis in whom treatment with methotrexate has not worked well enough.

Avtozma is used in combination with methotrexate for these conditions but it can be used on its own in patients for whom methotrexate is inappropriate.

Avtozma is also used to treat:

- adults with giant cell arteritis, a disease in which arteries, usually of the head, are swollen;
- adults and children from 2 years of age with severe or life-threatening cytokine release syndrome (CRS, a condition that can cause nausea, vomiting, pain and low blood pressure). CRS is a side effect of certain cancer treatments and Avtozma is used for CRS caused by medicines known as chimeric antigen receptors (CAR) T-cell medicines.

Avtozma can also be used in adults with COVID-19 who are receiving treatment with corticosteroid medicines by mouth or injection and require extra oxygen or mechanical ventilation (breathing assisted by a machine).

Avtozma contains the active substance tocilizumab and is a biological medicine. It is a 'biosimilar medicine'; this means that Avtozma is highly similar to another biological medicine (the 'reference

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medicine') that is already authorised in the EU. The reference medicine for Avtozma is RoActemra. For more information on biosimilar medicines, see here.

How is Avtozma used?

Avtozma can only be obtained with a prescription and treatment should be started by a doctor who has experience in the diagnosis and treatment of the relevant condition.

Avtozma is given by injection under the skin or by infusion (drip) into a vein. How Avtozma is given, the recommended dose and how often it is given depends on the condition it is used to treat. For COVID-19, Avtozma must only be given as an infusion.

For more information about using Avtozma, see the package leaflet or contact your doctor or pharmacist.

How does Avtozma work?

The active substance in Avtozma, tocilizumab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific target (called an antigen) in the body. Tocilizumab attaches to the receptor for a messenger molecule or 'cytokine' called interleukin-6. This messenger is involved in inflammation and is found at high levels in patients with rheumatoid arthritis, systemic juvenile idiopathic arthritis, juvenile idiopathic polyarthritis, giant cell arteritis, cytokine release syndrome and COVID-19. By preventing interleukin-6 from attaching to its receptors, tocilizumab reduces the inflammation and other symptoms of these diseases.

What benefits of Avtozma have been shown in studies?

Laboratory studies comparing Avtozma with RoActemra have shown that the active substance in Avtozma is highly similar to that in RoActemra in terms of structure, purity and biological activity. Studies have also shown that giving Avtozma produces similar levels of the active substance in the body to those seen with RoActemra.

In addition, Avtozma was as effective as RoActemra in improving symptoms of rheumatoid arthritis in a study involving 471 adults in whom previous treatment with methotrexate had not worked well enough. After 24 weeks of treatment, the DAS28 score (a measure of disease activity in rheumatoid arthritis) had decreased by an average of 3.0 both in patients receiving Avtozma and in those receiving RoActemra.

Because Avtozma is a biosimilar medicine, the studies on effectiveness and safety of tocilizumab carried out with RoActemra do not all need to be repeated for Avtozma.

What are the risks associated with Avtozma?

For the full list of side effects and restrictions of Avtozma, see the package leaflet.

The safety of Avtozma has been evaluated and, on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine RoActemra.

In patients with rheumatoid arthritis, systemic juvenile idiopathic arthritis, juvenile idiopathic polyarthritis, giant cell arteritis or cytokine release syndrome, the most common side effects with tocilizumab (which may affect more than 5 in 100 people) include upper respiratory tract (nose and throat) infections, nasopharyngitis (inflammation of the nose and throat), headache, hypertension (high blood pressure) and abnormal levels of the liver enzyme ALT. Some side effects can be serious.

The most frequent are serious infections, complications of diverticulitis (a disease affecting the gut) and hypersensitivity (allergic) reactions.

In patients with COVID-19, the most common side effects with tocilizumab (which may affect more than 5 in 100 people) include abnormal liver function tests, constipation, and urinary tract infections (infections of the parts of the body that collect and pass out urine).

Avtozma must not be used in patients who have an active, severe infection (except COVID-19). Doctors should monitor patients carefully for signs of infection during treatment and should prescribe Avtozma with caution in patients who have had recurring or long-term infections, or diseases that could increase the risk of infections, such as diverticulitis or diabetes.

Why is Avtozma authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Avtozma has a highly similar structure, purity and biological activity to RoActemra and is distributed in the body in the same way. In addition, a study in rheumatoid arthritis have shown that Avtozma and RoActemra are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Avtozma will have the same effects as RoActemra in its authorised uses. Therefore, the Agency's view was that, as for RoActemra, the benefits of Avtozma outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Avtozma?

The company that markets Avtozma must supply all doctors expected to prescribe the medicine for rheumatoid arthritis, systemic juvenile idiopathic arthritis, giant cell arteritis and juvenile idiopathic polyarthritis with an educational pack containing important information on the safety profile and correct use of Avtozma. The pack will also include a patient alert card with key safety information for patients.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Avtozma have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Avtozma are continuously monitored. Suspected side effects reported with Avtozma are carefully evaluated and any necessary action taken to protect patients.

Other information about Avtozma

Avtozma received a marketing authorisation valid throughout the EU on 14 February 2025.

Further information on Avtozma can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/avtozma.

This overview was last updated in 03-2025.