EMA/185914/2025
EMEA/H/C/005907

Aucatzyl (*obecabtagene autoleucel*)

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

What is Aucatzyl and what is it used for?

Aucatzyl is a medicine used to treat a type of blood cancer that affects B cells (a type of white blood cell) called B-cell precursor acute lymphoblastic leukaemia (ALL). It is used in adults aged 26 years and above whose cancer did not respond to or has come back after previous treatment.

Aucatzyl contains the active substance obecabtagene autoleucel (consisting of genetically modified white blood cells).

How is Aucatzyl used?

Aucatzyl must be given in a qualified treatment centre by a doctor with experience in the treatment of blood cancers and who is trained to treat patients with the medicine.

Aucatzyl is prepared using the patient's own T cells (a type of white blood cells) which are extracted from the blood and genetically modified in the laboratory. The medicine must only be given to the patient whose cells were used to make it. Before having Aucatzyl, the patient should have a short course of chemotherapy to clear away their white blood cells. Aucatzyl is given as two infusions (drips) into a vein, on day 1 and day 10 of treatment. Just before the infusion, the patient is given paracetamol and an antihistamine medicine to reduce the risk of reactions to the infusion.

Emergency equipment and a medicine called tocilizumab, or a suitable alternative if unavailable, must be available in case the patient has a serious side effect called cytokine release syndrome (CRS), a potentially life-threatening condition that can cause fever, vomiting, shortness of breath, pain and low blood pressure (see more information below).

Patients should be closely monitored for 14 days after the first infusion for side effects and are advised to stay close to a specialist hospital for at least 4 weeks after treatment.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Aucatzyl work?

Aucatzyl contains the patient's own T cells that have been modified genetically in the laboratory so that they make a protein called chimeric antigen receptor (CAR). CAR can attach to another protein on the surface of cancerous B-cell cells called CD19.

When Aucatzyl is given to the patient, the modified T cells attach to cancer cells and kill them, thereby helping to clear the cancer from the body.

What benefits of Aucatzyl have been shown in studies?

In the main study, 94 adults with B-cell precursor ALL whose cancer did not respond to or had come back after previous treatment received an infusion of Aucatzyl. In this study, Aucatzyl was not compared to any other treatment or a placebo (dummy treatment).

Among patients who received Aucatzyl, around 77% (72 out of 94) responded overall which means they had no signs of cancer but blood cell counts may not have returned to normal, and 55% of all the patients (52 out of 94) responded with their blood counts returning to normal.

What are the risks associated with Aucatzyl?

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

The most common side effects with Aucatzyl (which may affect more than 1 in 10 people) include CRS, infections, pain including musculoskeletal (muscle and bone) pain, fever, nausea (feeling sick), diarrhoea, headache, tiredness and bleeding.

Some side effects can be serious. The most frequent (which may affect more than 1 in 10 people) include infections and febrile neutropenia (low levels of white blood cells with fever). Other serious side effects (which may affect up to 1 in 10 people) include a neurological disorder called ICANS (immune effector cell-associated neurotoxicity syndrome), CRS, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage) and fever.

Why is Aucatzyl authorised in the EU?

The main study showed that Aucatzyl is effective in treating B-cell precursor ALL in adults whose cancer did not respond to, or had come back after, previous treatment

The study did not compare Aucatzyl with another cancer medicine or a placebo. At the time of evaluation there were only limited treatment options for patients with B-cell precursor ALL aged above 26 years. Therefore, the medicine was considered to address an unmet medical need in this patient group.

In terms of safety, Aucatzyl has some important side effects, which are similar to other treatments of the same class and are considered acceptable given the seriousness of the disease. The main issues are cytokine release syndrome (CRS), neurological problems (ICANS), low white blood cell count (leukopenia) and infection, but these can be managed by closely monitoring the patient.

Aucatzyl has been given conditional authorisation. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Aucatzyl. It must submit results from two studies on the long-term safety and effectiveness of the medicine. Every year, the Agency will review any new information that becomes available.

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

The company that markets Aucatzyl must ensure that hospitals where Aucatzyl is given have appropriate expertise, facilities and training. Tocilizumab or a suitable alternative must be available in case patients develop CRS. The company must provide educational materials for healthcare professionals and an alert card for patients with information about possible side effects, especially CRS and ICANS.

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

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

Other information about Aucatzyl

Aucatzyl received a conditional marketing authorisation valid throughout the EU on 17 July 2025.

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

This overview was last updated in 07-2025.