



EUROPEAN MEDICINES AGENCY
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Korjunny (*catumaxomab*)

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

What is Korjunny and what is it used for?

Korjunny is a medicine used to treat adults with malignant ascites (a build-up of fluid in the abdomen) caused by cancers that are EpCAM-positive (meaning that the cancer cells have a molecule on their surface called epithelial cellular adhesion molecule). Korjunny is used in patients who cannot have any further cancer treatment.

Korjunny contains the active substance catumaxomab.

How is Korjunny used?

The medicine can only be obtained with a prescription and should be given under the supervision of a doctor experienced in the use of cancer medicines. Before starting treatment, patients should be tested to ensure that the cancer cells are EpCAM-positive.

Korjunny is given by perfusion (a slow injection using a pump) into the abdomen (belly) over at least 3 hours, on days 0, 3, 7 and 10 of treatment. After the first dose, patients must remain in hospital for 24 hours to be monitored for certain side effects. For subsequent doses, patients must stay in hospital for 6 hours or longer if the doctor deems it necessary.

Korjunny can cause inflammatory reactions including cytokine release syndrome (CRS, a condition that can cause fever, nausea, vomiting, pain and low blood pressure) and systemic inflammatory response syndrome (SIRS, inflammation throughout the body). Before each infusion, it is recommended that patients take medicines against pain, fever and inflammation to prevent symptoms of inflammation in the body.

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

How does Korjunny work?

The active substance in Korjunny, catumaxomab, is a monoclonal antibody (a type of protein) designed to recognise and attach to 2 proteins: EpCAM, a molecule found on certain cancer cells, and CD3, a protein found on T cells, a type of cell of the immune system (the body's natural defences). By bringing cancer cells and T cells close together, catumaxomab promotes the killing of cancer cells by

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T cells. Catumaxomab also attaches to a third protein called Fc-gamma receptor which helps the cells of the immune system to attack cancer cells.

All these actions cause the death of cancer cells in the abdomen, removing a major cause of excessive abdominal fluid.

What benefits of Korjunny have been shown in studies?

Korjunny was shown to prolong the time patients with malignant ascites caused by EpCAM-positive cancers live without requiring further paracentesis (a procedure in which a needle is inserted in the abdomen to drain fluid).

A main study involved 258 patients with malignant ascites and EpCAM-positive cancer who had either been previously treated with chemotherapy or for whom chemotherapy was not a suitable treatment. Patients given Korjunny and paracentesis lived for an average of 46 days without the need for further paracentesis, compared with 11 days for patients treated with paracentesis alone.

What are the risks associated with Korjunny?

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

The most common side effects with Korjunny (which may affect more than 1 in 10 people) include fever, abdominal pain, nausea (feeling sick) and vomiting.

The most important side effects with Korjunny include SIRS and liver failure.

Why is Korjunny authorised in the EU?

Although there was some uncertainty about the beneficial effect of Korjunny, the overall data show that Korjunny prolongs the time adults with malignant ascites caused by EpCAM-positive cancers live without the need for paracentesis, indicating lower fluid build-up after treatment with Korjunny.

Regarding quality of life, Korjunny may alleviate symptoms of the disease shortly after treatment but giving the medicine requires hospitalisation. Concerning safety, side effects occur more frequently with Korjunny than with paracentesis only, with symptoms of inflammation (nausea, vomiting and fever) and abdominal pain being the most common. The safety profile of Korjunny was however considered acceptable for the condition it is used for.

The European Medicines Agency therefore decided that Korjunny's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Korjunny will provide patients with a patient card including information on the signs and symptoms of CRS and SIRS and when to seek urgent help from a healthcare professional. The patient card will also inform healthcare professionals that the patient is being treated with Korjunny and provide the contact details of the prescribing doctor.

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

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

Other information about Korjuna

Korjuna received a marketing authorisation valid throughout the EU on 10 February 2025.

Further information on Korjuna can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/korjuna.

This overview was last updated in 11-2024.