EMA/121332/2025
EMEA/H/C/006433

Trabectedin Accord (*trabectedin*)

An overview of Trabectedin Accord and why it is authorised in the EU

What is Trabectedin Accord and what is it used for?

Trabectedin Accord is a cancer medicine used to treat adults with:

- soft-tissue sarcoma, a type of cancer that develops from the soft, supporting tissues of the body. Trabectedin Accord is used in patients whose cancer is advanced (has started spreading) when anthracyclines and ifosfamide (other cancer medicines) have stopped working or when patients cannot take these medicines;
- ovarian cancer (cancer of the ovaries) that has relapsed (come back after previous treatment) and is responding to platinum-based chemotherapy. In these patients, Trabectedin Accord is used in combination with pegylated liposomal doxorubicin (PLD, another cancer medicine).

Trabectedin Accord contains the active substance trabectedin and is a 'generic medicine'. This means that Trabectedin Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Trabectedin Accord is Yondelis. For more information on generic medicines, see the question-and-answer document here.

How is Trabectedin Accord used?

Trabectedin Accord must be given under the supervision of a doctor experienced in the use of chemotherapy. It should only be used by qualified oncologists (cancer specialists) or other health professionals specialised in giving cytotoxic (cell-killing) medicines.

Trabectedin Accord is given as an infusion (drip) into a large vein just above the heart, every 3 weeks. For soft-tissue sarcoma, each infusion lasts 24 hours, while for ovarian cancer, it lasts 3 hours. Treatment with Trabectedin Accord can continue as long as the patient benefits from it.

Patients will be given medicines before each infusion to prevent vomiting, nausea (feeling sick) and liver damage.

The medicine can only be obtained with a prescription. For more information about using Trabectedin Accord, see the package leaflet or contact your doctor or pharmacist.

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How does Trabectedin Accord work?

The active substance in Trabectedin Accord, trabectedin, is a chemotherapy. It works by attaching to and damaging the DNA. This stops cancer cells from dividing, leading to their death and preventing the growth of the cancer.

How has Trabectedin Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Yondelis, and do not need to be repeated for Trabectedin Accord.

As for every medicine, the company provided studies on the quality of Trabectedin Accord. There was no need for 'bioequivalence' studies to investigate whether Trabectedin Accord is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Trabectedin Accord is given by infusion, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Trabectedin Accord?

Because Trabectedin Accord is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Trabectedin Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Trabectedin Accord has been shown to be comparable to Yondelis. Therefore, the Agency's view was that, as for Yondelis, the benefits of Trabectedin Accord 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 Trabectedin Accord?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Trabectedin Accord have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Yondelis also apply to Trabectedin Accord where appropriate.

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

Other information about Trabectedin Accord

Trabectedin Accord received a marketing authorisation valid throughout the EU on 25 April 2025.

Further information on Trabectedin Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/trabectedin-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 04-2025.